



Country Profile

The organisation of Food Safety,
Animal Health, Animal Welfare and
Plant Health Control Systems

Bulgaria

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INTRODUCTION

This overview has been drawn up by the Food and Veterinary Office (FVO), a Directorate of the Directorate-General for Health and Consumers of the European Commission based on information supplied by Bulgaria.

The aim is to present, in summary form, the latest information on how control systems for food and feed safety, animal health, animal welfare and plant health are organised in Bulgaria.

Chapter 1 describes the overall organisation of the Bulgarian authorities and the respective responsibilities of the Ministries and Government agencies in relation to the different components of the control system. A chart is used to help the reader better understand the inter-relationships between the responsibilities of the different bodies.

Chapter 2 gives a more detailed description of the main responsibilities for each of the eleven separate systems that form the complete range of control systems in Bulgaria, covering the whole chain of plant, animal and food production. As in Chapter 1, organisation charts are used to help the reader.

Annex I provides details on the number of control staff in Bulgaria. The statistics on staff resources have been provided by the Member States on a non-standardised basis.

The overview was updated following the most recent general follow-up audit in September 2011 and will be updated at regular intervals based on relevant information received by the Commission from the Bulgarian authorities.

Acronyms are used extensively throughout this overview for the sake of brevity. A list of acronyms, abbreviations and special terms is given in Annex II as a guide for the reader.

SUMMARY

A particular strategy was followed during this specific General Follow-up Audit (GFA). The strategy started by an intensive round of consultation at FVO level in order to determine SANCO priority areas in Bulgaria.

The Minister of Agriculture and Food and the Minister of Health perform state policy in the field of food safety. Within the Ministry of Agriculture and Food (MAF), the Animal Health and Food Safety Directorate (AHFSD) is responsible for the development and coordination of the implementation of MAF policy in the field of food safety and quality, feed safety, animal health and welfare. The Bulgarian Food Safety Agency (BFSA) under the Ministry of Agriculture and Food is the competent authority performing official control of food safety and food quality, feed, plant protection products and fertilizers, animal by-products, animal health and welfare, and plant health.

The Ministry of Health (MH) is also responsible in developing food safety policy in the field of food of non animal origin. PHD has as well the role of co-ordination and supervision of official controls on bottled natural mineral, spring and table waters, performed by the 28 Regional Health Inspectorates (RHI).

Bulgaria is divided into 28 regions. The regions are administrative units executing the regional policy of central government bodies. The regional governors are appointed by the Council of Ministers. Local government is organised through 264 municipalities. At regional level BFSA has 28 Regional Food Safety Directorates (RFSD) responsible for the implementation of the official controls.

The first Multi Annual National Control Plan (2008-2010) (MANCP) was approved by the National Council for Co-ordination of Controls in October 2008. The plan is structured vertically according to the competent authorities involved in official controls and was prepared in accordance with Commission Decision 2007/363/EC. The MANCP has been amended and prolonged till the end of 2011 in order to ensure the effective starting and functioning of the BFSA from the beginning of 2011. An Order of Minister of Agriculture and Food (RD 09-649/10.08.2011) for establishing of a working group for preparation of the new MANCP (January 2012-December 2014) has been signed. The new MANCP is published on the website of the Ministry of agriculture and food: <http://www.mzh.government.bg/MZH/bg/ShortLinks/ZJBH/zakon.aspx>

The 2010 annual report on the implementation of the MANCP was provided to the Commission in July 2011 and is published on the [Ministry of Agriculture and Food website](#).

1 ARRANGEMENTS FOR THE IMPLEMENTATION OF CERTAIN REQUIREMENTS OF REGULATION (EC) N° 882/2004

Designation of competent authorities

The Minister of Agriculture and Food and the Minister of Health perform state policy in the field of food safety.

The BFSA under the MAF is the competent authority performing official control of food safety and food quality, feed, food contact materials, plant protection products and fertilizers, animal by-products, animal health and welfare, and plant health. The MH is responsible for the controls on bottled natural mineral, spring and table waters carried out by the RHIs.

Ministry of Agriculture and Food

The framework legislation for food and feed safety controls comprises: Law on BFSA (SG 8/2011); Food Law (SG No 102/2003, last amended SG No 8/2011); Veterinary Activity Law (SG No 87/2005, last amended SG No 92/2011); Feed Law (SG No 55/2006, last amended SG No 8/2011) and the Plant Protection Law (SG No 91/1997, last amended SG No 28/2011). Detailed requirements are set out in specific Ordinances.

The administration in the food safety sector is organised in line with the territorial division of the country. The territory of the Republic of Bulgaria is divided into 28 regions which execute the regional policy of central government bodies. The Regional Governor is appointed by the Council of Ministers. Local government in Bulgaria is organised through 264 municipalities.

Animal Health and Food Safety Directorate (AHFSD)

The Directorate is responsible for development and co-ordination of the implementation of MAF policy in the field of food safety and quality, feed safety, animal health and welfare. The Directorate is responsible for harmonisation of legislation and co-ordination of the control authorities within the Ministry. Experts from the Directorate participate in activities on performance of audit of the official control carried out by the Bulgarian Food Safety Agency in accordance with art. 4 (6) of Regulation (EC) № 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The Directorate represents the Ministry at international forums including WHO, FAO and Codex Alimentarius.

The main tasks of the AHFSD are to:

- Develop and co-ordinate the implementation of MAF policy in the field of food safety and quality, feed safety, animal health and welfare;
- Draft legislative acts and amendments of the current legislation in the field of food and feed safety, animal health and welfare;
- Prepare the MANCP in accordance with Regulation (EC) 882/2004 and the annual report on its implementation;
- Co-ordinate the work of the control bodies, laboratories and other national bodies within MAF performing official feed and food control;

- Participates with experts in the performance of audits of official control on control bodies within the MAF, performing official feed and food control;
- Co-ordinate and manage the control bodies within the MAF during the preparation of contingency plans for food and feed;
- Receive applications for the placing on the market of Genetically Modified Organisms (GMOs) according to Directive 2001/18/EC, and participate in the Consultative Commission on GMOs, as well as, maintaining the register of authorised GMOs;
- Receive applications for the initial placing on the market of Genetically Modified Feeds;
- Function as the national contact point for the Rapid Alert System for Food and Feed (RASFF);
- Function as a National Contact Point for Codex Alimentarius;
- Participate in joint activities of EFSA, WHO, FAO, Codex Alimentarius and other international organisations in the field of food and feed safety, animal health and welfare;
- Prepare Bulgaria's position for participation in Council meetings, working groups and meetings of the Standing Committee on Food Chain and Animal Health (SCFCAH) in the field of food and feed safety, animal health and welfare;
- Participate in EU working groups and meetings of SCFCAH in the field of food and feed safety, animal health and welfare.

Bulgarian Food Safety Agency (BFSA)

The BFSA is a specialised body of the MAF. It was created with the adoption of the Law on the BFSA in January 2011 (*SG 8/2011*). The BFSA is in operation since mid-February 2011 when its Code of Organisation was published in the State Gazette (*SG 15/2011, last amended SG 59/2011*). The BFSA incorporates the former National Veterinary Service (NVS), the former National Plant Protection Service (NPPS) and the former National Grain and Feed Service (NGFS), as well as the regional food health inspectors, who were responsible for the control of food of non animal origin in the Regional Health Inspections (former Regional Inspections for Public Health Protection and Control) under the MH and the quality compliance of fresh fruits and vegetables (under MAF) with the European Commission (EC) standards for placing on the market.

The BFSA is the competent governmental authority for carrying out official controls in Bulgaria in terms of phytosanitary issues; plant protection products and fertilizers; veterinary activities; animal health and welfare; animal by-products not intended for human consumption; feedingstuffs; raw materials and foodstuffs with the exception of bottled natural mineral, spring and table water; materials and articles intended for contact with food; and the quality compliance of fresh fruits and vegetables with the European Commission (EC) standards for placing on the market.

The agency has its central office in Sofia. It has also 28 Regional food safety directorates (RFSD) distributed across the country.

Risk Assessment Centre

With the adoption of the Law on BFSA and its Code of Organisation, a Risk Assessment Centre (RAC) was created, managed by a Management Board and assisted by an Advisory Board. The RAC provides independent scientific assessment of risks related to food safety, human health, animal health and welfare, food and feed additives, GMOs, dietetic products, nutrition and allergens, materials and articles intended for contact with food, enzymes, flavourings and supporting substances, biological hazards, contaminants, plant health and plant protection.

Ministry of Health

Public Health Directorate

The PHD develops the food safety policy including the official controls on bottled natural mineral, spring and table waters and the nutrition of the different population groups.

The main tasks of PHD are to:

- Develop and co-ordinate the implementation of MH policy in the field of food of non animal origin, bottled natural mineral, spring and table waters and the nutrition of the population as a whole;
- Prepare legislative acts and amendments of the current legislation in the field of horizontal legislation and food of non animal origin with the MAF;
- Participate in the preparation of the MANCP in accordance with Regulation (EC) 882/2004 and the annual report on its implementation;
- Co-ordinate the official control of the regional bodies on bottled natural mineral, spring and table waters and the nutrition of the population and execute the procedures for the recognition of the natural mineral waters;
- Co-ordinate the work of the laboratories within MH performing official food analyses;
- Develop instructions, guidelines, opinions and plans of action for the implementation of the legislation in the field of bottled natural mineral, spring and table waters and the nutrition of the population;
- Prepare and co-ordinate training activities of the regional control bodies within the MH;
- Receive applications for the placing on the market of Genetically Modified Foods, (GMFs) and Novel Foods, registration of food irradiation facilities and registration of its activities;
- Function as a competent contact point for the RASFF;
- Participate in joint activities of EFSA, WHO, FAO, Codex Alimentarius and other international organisations in the field of food safety and nutrition, natural mineral waters;
- Prepare Bulgaria's position for participation in Council meetings, working groups and SCFCAH meetings for which it is designated by an order of the Minister of Health;
- Participate in EU working groups and meetings of the SCFCAH in the field of food safety.

Institutes, Laboratories and other bodies

Laboratory network between the BFSA

According to Article 24 of the rules of the BFSA, the main tasks of the Laboratory Activities Directorate (LAD) are to:

- Co-ordinate laboratory diagnostic tests;
- Collect, analyse and summarise information on the performance of laboratory and diagnostic activities in the agency system;
- Participate in the development of programs for training and qualification of laboratory specialists from the agency;
- Prepare and co-ordinate the implementation of the National monitoring program to control residues of veterinary medicinal and environmental contaminants in animal feed and other products of animal origin and GMO;
- Participate in the preparation of the State prevention program, participate in programs for surveillance and eradication of animal diseases and co-ordinate their implementation in the laboratory and diagnostic tests;
- Participate in drafting the MANCP;
- Co-ordinate and organise inter-laboratory comparison and proficiency testing of laboratories associated with the activities of the agency and EU reference laboratories;
- Assist the laboratories in the preparation for accreditation, re-accreditation and extension of the scope of accreditation;
- Make proposals to the Executive Director for identification of the laboratories that will conduct research for the purposes of official control under European law.

NRLs within the BFSA according to Order RD 09-773/15 09 2011 from MAF:

1. National Diagnostic and Research Veterinary (Medical) Institute (NDRVI) – National Reference Centre on Safety of Food of Animal Origin: within this laboratory the following NRLs are defined:
 - NRL Salmonella, campylobacter and antimicrobial resistance (AMR)
 - NRL Listeria and Escherichia coli
 - NRL Marine biotoxins
 - NRL Water content in poultry meat
 - NRL Animal proteins in feedingstuffs

By the end of June 2012 the National Reference Centre for Food Safety (NRCFS) will enter its documents into “Bulgarian Accreditation Service” Executive Agency to receive enhanced scope of accreditation by inclusion in its scope methods for diagnosis of campylobacter spp. in meat and meat products; methods for detection of content of trans isomers of fatty acids in vegetable oils and butters, and in milk and milk products; methods for detection of fat content in milk and milk products; smears for food contact surfaces; isolates for determination of microbial resistance (salmonellas, staphylococcae, E. colli, and entero-coccae); methods for proving salmonellas, lysteria and campylobacter in control and confirmative feed samples. The forthcoming audit to be performed by the "Bulgarian Accreditation Service" Executive Agency will involve into the scope of accreditation the reference statute on activities related to antimicrobial resistance. The reference activities concerning the proof of verotoxigenic E.

coli. Are not involved into the scope of accreditation due to practical difficulties in calibration of RT-PCR.

2. NDRVI – National Reference Centre on Animal Health (NRCAH): within this laboratory the following NRLs are defined:

- NRL Rabies and monitoring the effectiveness of rabies vaccination
- NRL Brucellosis
- NRL Transmissible spongiform encephalopathies (TSE)
- NRL Parasites (in particular Trichinella, Echinococcus and Anisakis)

- NRL Leptospirosis

- NRL Tuberculosis and Anthrax
- NRL Enzootic bovine leucosis

With regard to enhancing the scope of the National Reference Centre for Animal Health (NRCAH) by adding methods for detection of pesticides in feed, there is a detailed program developed for relevant training of the staff to be involved in these new methods. It is envisaged that about the end of October 2012 respective laboratory will start pilot testing of real feed samples. The method is to be included in the 2013 plan for enhancing the methods within accreditation scope of the NRCAH.

3. NDRVI - Testing Laboratory for exotic and extremely dangerous infections. Within this laboratory the following NRLs are defined:

- NRL Classical Swine Fever (CSF) and African swine fever;
- NRL Foot-and-mouth disease and swine vesicular disease;
- NRL African horse sickness;
- NRL Avian influenza and Newcastle disease;
- NRL Bluetongue.

NDRVI has also its two country units located in the towns of Veliko Tarnovo and Stara Zagora, where serological diagnostics of CSF is performed.

The Regional Testing Laboratory in Stara Zagora has entered its documents into “Bulgarian Accreditation Service” Executive Agency to receive enhanced scope of accreditation by inclusion therein methods for TSE diagnostics and methods for serological diagnosis of brucellosis, leucosis and leptospirosis on 14.02.2012 (of entry ref. No. № 08-07/P/14.02.2012). By its letter of exit ref. No. 104/233ЛИ/1/ф/30.03.2012, Bulgarian Accreditation Service” Executive Agency has notified the RTL in Stara Zagora that respective procedure has been opened on the basis of the application entered therein.

The Regional Testing Laboratory in Veliko Tarnovo has entered its documents into “Bulgarian Accreditation Service” Executive Agency to receive enhanced scope of accreditation by inclusion therein methods for TSE diagnostics and methods for serological diagnosis of brucellosis, leucosis and leptospirosis on 14.02.2012 (of entry ref. No. 08-06/P/14.02.2012. By its letter of exit ref. No. 105/232ЛИ/1/ф/30.03.2012 Bulgarian Accreditation Service” Executive Agency has notified the RTL in Veliko Tarnovo that respective procedure has been opened on the basis of the application entered therein.

4. NDRVI - Testing Laboratory for fish diseases and mollusc diseases. Within this laboratory the following NRLs are defined:
 - NRL Fish diseases, mollusc diseases and crustacean diseases.
5. The Central Laboratory for Veterinary Control and Ecology (CLVCE). Within this laboratory the following NRLs are defined:
 - NRL for residues of anabolic medicines and unauthorised substances in biological fluids, raw materials and food of animal origin (Group A (1), (2), (3), (4), (5) and (6) to Directive 96/23/EU);
 - NRL for residues of veterinary medicines in biological fluids, raw materials and food of animal origin (Group B (1), (2)(a), (b), (d), (e) and B (3)(e) to Directive 96/23/EU);
 - NRL for residues of environmental contaminants in raw materials and food of animal origin (B (2)(c), (3)(a), (3)(b), (3)(c) and (3)(d) to Directive 96/23/EU);
 - NRL for residues of gamma-emitting radionuclides in water, beverages, feed, raw materials and food (B (3)(f) to Directive 96/23/EU);
 - NRL for safety and quality of honey and bee products.

The CLVCE have included in their scope of accreditation all analyses recovered in 2012, whose scope was limited in 2010. The new methods which are being developed in CLVCE are: determination of quinolones in matrix honey by HPLC; determination of NSAIDs in matrix milk by LC/MS (under development for matrix meat); and determination of nitrofurans by LC/MS and ELISA. The laboratory' is expanding the number of certain groups of contaminants such as chemical elements (new equipment - ICP-OES); under development are pesticides and pyrethroids.

6. Central Laboratory for Chemical Testing and Control (CLCTC). Within this laboratory the following NRLs are defined:
 - NRL for single pesticide residue methods;
 - NRL for pesticide residues in fruits and vegetables including commodities with high water and high acid content;
 - NRL for mycotoxins in foods of plant origin.

Together with the LAD of the BFSA, this laboratory is responsible for drafting and implementation of the National Monitoring Programme for Pesticide Residues in food of plant origin. It is also responsible for official control of plant protection products and fertilizers. CLCTC is accredited to EN ISO/IEC 17025 for all its activities and is the NRL for both pesticide residues in fruits and vegetables and single pesticide residues methods, as well as mycotoxins analysis of plant products.

7. Food Safety and Quality Laboratory in the RFSD. Within this laboratory the following NRL is defined:
 - NRL Milk and milk products.

Within BFSA there are nine Regional Testing laboratories (RTL) located in the following RFSD – RFSD Sofia city, RFSD Blagoevgrad, RFSD Vratsa, RFSD Gabrovo, RFSD Plovdiv, RFSD Sliven, RFSD Haskovo, RFSD Shumen and RFSD Varna. The laboratories are accredited according to the requirements of EN ISO/IEC 17025 and carry out tests in the area of food and feed safety and animal

health. The RTL carry out tests of samples taken from more than one region in the country according to a distribution schedule. Their work is methodologically co-ordinated by the NRLs.

All nine RTLs within the RFSD and the NRC on Safety for foodstuffs of animal origin will include in their scope of accreditation analysis on food of non-animal origin in 2012. As by now, the 8 regional laboratories with the RFSDs in Varna, Blagoevgrad, Sofia-town, Vratsa, Shumen, Haskovo, Gabrovo and Plovdiv have their relevant documents entered into and processed by the "Bulgarian Accreditation Service" /BAS/ Executive Agency to request enhancement of the scope of their accreditation related to foodstuffs of non-animal origin. Their auditing by BAS Executive Agency has been completed.

Central Laboratory for Plant Quarantine (CLPQ):

This is the official reference laboratory as regards plants, plant products and harmful organisms. It carries out phytosanitary laboratory analyses; final diagnostics and identification of harmful organisms; investigates tests and introduces new methods of analysis and ways to control the quarantine of pests; prepares information materials on quarantine pests and carries out training of phytosanitary specialists. It is located in Sofia and has a branch in Samokov. The CLPQ supervises the activity of seven Regional and Border Inspection Posts' (BIP) laboratories, validates positive and suspect results and issues the methodology for analyses. It is also involved in co-ordinating regional activities, issuing methodological guidelines for inspection and drafting monitoring programmes.

The National Centre of Public Health and Analyses (NCPHA) is a research institute in the field of public health and food safety, under the MH. It also assists other governmental bodies, municipal authorities and non-governmental organisations. It carries out applied research activities and works on capacity-building in the area of health care. Experts of the NCPHA participate in the risk assessment of food additives, food contact materials, pesticide residues, contaminants - mycotoxins, nitrates, microbiological contaminants, GMO and nutrients, carried out by the RAC within the BFS. Its laboratories are accredited since 2003 according to EN ISO/IEC 17025 by the National Accreditation Board. Two of the laboratories are the NRL for GM foods and food contact materials. The NCPHA develops and implements methods of analysis and organises training of laboratory staff from the RHI.

National laboratory network under the Ministry of Health

Laboratory analyses of food of non animal origin, including mineral waters, for the purposes of the official controls are carried out by six of the 28 laboratories of the RHI (Order No RD 09-155 of 04.04.2008). These are the laboratories in Sofia, Plovdiv, Pleven, Varna, Burgas and Veliko Tarnovo. The laboratories co-ordinate their day-to-day activities based on sampling plans developed at national level in the MH. The NCPHA is responsible for methodological guidance of the RHI laboratories. All six laboratories are accredited to EN ISO/IEC 17025. In the NCPHA there are two NRL – NRL for GMO foods and NRL for food contact materials.

National Accreditation Body

The Executive Agency ‘Bulgarian Accreditation Service’ (BAS) under the Ministry of Economy, Energy and Tourism is the national accreditation body for testing and calibration of laboratories, product certification bodies, management systems,

certification bodies, personnel certification bodies and inspection bodies. It also performs inspection and certification of compliance of laboratories with Good Laboratory Practice.

BAS has been accepted as a full member of the European Co-operation for Accreditation-EA. The Service operates on the bases of the EN 45000, EN ISO/IEC 17000 series of standards and the EA and ISO/IEC guidance documents. The Service develops and implements a variety of regulations, norms, procedures, documents and organisational practices.

The Accreditation Law (SG 100/2005, last amended SG 42/2009) lays down the structure and activities of BAS, as well as, the conditions on accreditation of the bodies performing testing, calibration, certification of products, certification of management systems, certification of personal and, control and environment inspection bodies. The process of accreditation follows the conditions and procedure set down in the Law and in the BAS procedures and rules of accreditation. The procedures and rules of accreditation are published in the Bulgarian State Gazette and on the Internet.

Risk assessment centre

The RAC is an independent legal body within the BFSa. RAC co-ordinates independent scientific risk evaluation according to food and feed safety, animal health and welfare, plant health and plant protective products.

RAC informs the public and stakeholders about problems connected to food and feed safety, animal and plant health and for necessary corrective measures.

According to the Law on the BFSa, all functions of the National Council for Food Safety, Expert Council and National Council for Co-ordination of Controls are implemented by the BFSa and respectively the RAC.

Co-ordination between Competent Authorities

BFSa is the CA carrying out official control on food throughout the country, with the exception of bottled natural mineral, spring and table waters.

Co-ordination and co-operation between competent authorities at the operational levels takes place via various agreements between the competent authorities and joint control programmes (e.g. BFSa and Customs; MAF and MH for monitoring programmes). Agreement № RD 28-280 was signed between MAF and MH on 12.10.2011 in this regard. The RAC plays an important role in the co-ordination and co-operation between CAs.

According to the CAs, the creation of the agency has and will improve co-ordination and co-operation as all previous services involved in the control of foodstuffs are now mostly under a single body. To be able to assess if this has really improved and is adequate, it will require waiting for the results of future audits.

Co-operation within Competent Authorities

The AHFSD is responsible for developing and co-ordination of the implementation of MAF policy in the field of food safety and quality, feed safety, animal health and welfare, harmonisation of legislation and co-ordination of the control authorities within the MAF and with other ministries and institutions.

See above.

Delegation of specific tasks related to official controls

There are no delegated control bodies.

Contingency planning

Contingency plans are drawn up for most OIE listed diseases.

Apart from a number of contingency plans drafted by the BFSA for animal health emergency situations, the following general emergency plans have been established:

- Operation action plan in emergency situations (BFSA)
- Action Plan for Emergency Situations related to Feed (BFSA)
- Plant protection contingency plans (BFSA)
- Contingency plan for food emergencies (MH, BFSA)

A detailed description of the individual plans is provided in the MANCP.

See also section 2.1. for more information.

Resources for performance of controls

Legal powers for controls

The framework legislation provides the CAs with the necessary legal powers to carry out controls, including the powers of access to food business premises and documentation. There is an obligation on food/feed business operators to undergo inspection by the competent authorities. The framework legislation for food and feed safety controls comprises the Law on the BFSA (SG No 8/2011); Food Law (SG No 102/2003, last amended SG No 8/2011); the Veterinary Activity Law (SG No 87/2005, last amendment SG No 92/2011); the Feed Law (SG No 55/2006, last amended SG No 8/2011) and the Plant Protection Law (SG No 91/1997, last amended SG No 28/2011) and the Law of Health, last amended SG No 40/2012).

See also measures in case of non-compliance below.

Staffing provision and facilities

In total 2798 staff are involved in controls on food and feed safety, animal health and animal welfare, and plant health within the BFSA. Under the MH, 43 staff are involved in the control of bottled natural mineral, spring and table waters.

Details of staff resources for all services are provided in Annex I of the country profile.

BFSA

Each Food Control Department (FC Department) within the RFSD has calibrated thermometers and equipment for proper transportation of samples of food.

All inspectors from the PHD within the RFSD who are authorised to perform control activities are provided with the following materials, instruments and equipment:

1. Inspection documentation – forms and reports filled in quadruplicate during the inspection; one copy is submitted to the representative of the site visited.
2. Sampling for analyses – labels, stick-on band with BFSA's logo, polyethylene bags, drills and other materials.

3. Self-protection devices – protection clothes, latex gloves, face-guards.
4. All BIPs are fully equipped according to the requirements set out in Annex 6 of Council Directive 2000/29/EC and Annex 6 of Ordinance No. 1 on phytosanitary control: office equipment, inspection tables for carrying out checks, binoculars, microscopes, sieves, magnifying glasses, glass-ware, etc. There are also equipped loading platforms for load handling operations and warehouse premises for storage of consignments under quarantine.
5. As regards the phytosanitary control on production, each phytosanitary department is provided with suitable motor vehicles to reach every investigated area, regardless of terrain. Each vehicle is fully equipped with all the necessary devices for sampling, packing, sealing, disinfectants, etc.

In 2012, the necessary equipment for official controls of animal welfare requirements has been procured for all the 28 Regional Food Safety Directorates (RFSD) of the country. The relevant cascade training has been performed for official veterinarians on the spot that are performing official controls. As by now, 8 regional laboratories with the RFSD of Varna, Blagoevgrad, Sofia, Vratsa, Shumen, Haskovo, Gabrovo and Plovdiv have their documents entered to receive enhanced scope of accreditation concerning foodstuffs of non-animal origin. The audit there have already been performed by Bulgarian Accreditation Service” Executive Agency.

Conflict of interest

The Law on Conflict of Interest and the Law on the Civil Service prescribes the obligation of public officials as regards independence and involvement in other activities. Each public official has to sign annually a declaration that he/she has no conflict of interest and a declaration on the property owned (civil service law). There is also the code of ethics developed by the MAF.

There is a system of signals of possible conflict of interest developed at the level of each competent authority. These signals can be lodged by individual citizens, civil servants, colleagues etc. Competent authority has developed the procedures/internal rules on dealing with signals on conflict of interest. Rotation of inspectors is also used with the same aim.

Staff qualifications and training

Animal Health and Food Safety Directorate

The training needs of experts from the AHFSD are defined by:

- New legislation;
- Annual attestations of experts carried out by the Director of the AHFSD according to the Ordinance on Conditions and the Order on Attestations of officials in State administration. The attestation contains training on the basis of the working plan for the next year of the expert and on the basis of his/her professional experience.

Individual training plans are available for all staff, which includes induction training, training relevant to the job and also some general training such as languages. These plans are approved by the Director to ensure that they match the job description and the training needs identified. A training procedure for experts of AHFSD has been developed and approved. The procedure is published on the webpage of MAF. Training records are kept for all experts of the directorate (record of participation on training courses and qualification of experts).

Pursuant to Article 6 of Regulation (EC) № 882/2004, experts of the AHFSD participate in training to achieve a uniform approach and harmonised procedures for implementing the requirements of European legislation. Experts are trained in the regulations of the hygiene package, food and feed, animal health and welfare.

In 2010, under the program Better Training for Safer Food (BTSF) of the European Commission, DG Health and Consumers, experts from the AHFSD have obtained certificates for their participation in training courses on 19 topics.

In the period from January to December 2011 under the same program, 12 experts have participated in training sessions on 9 topics. After completion of the training, each expert drafts a report and provides it together with all the presentations and information received during the training for use by all experts from the directorate, colleagues from BFSA and stakeholders.

Information on training on various topics is available on the website of the MAF (<http://www.mzh.government.bg/MZH/bg/ShortLinks/ZJBH/Obuchenia/MaterialiObuchenia.aspx>).

In 2010, during the implementation of the project "Good governance, transparency and efficiency of the MAF", under the Operational Programme for Administrative Capacity-OPAC, 10 experts from the Directorate were involved in 5 modules of the project.

Experts from the directorate performing audit of the BFSA are trained in the standards of BS EN ISO 9001:2008 and BS EN ISO 19011:2004.

Recording and archiving of all training participation documents is done by an expert in the Directorate, who has been assigned responsibilities for the training of competent authorities.

With the creation of the BFSA, a new contact point within BFSA was nominated to co-ordinate the activities under the BTSF programme.

Bulgarian Food Safety Agency

With the foundation of the BFSA in February 2011, a special Training and Qualification Directorate (TQD) was created to co-ordinate the training and the qualifications of the employees of BFSA, including training by the European Commission, international organisations and third parties. Since July 2011 the National Contact point for BTSF programme is within the TQD of BFSA.

In the period from May to December 2011 under the BTSF program, a total of 61 experts from BFSA have participated in training sessions on 23 topics. After completion of the training, each expert drafts a report and provides it together with copy of certificate and report for conducted cascade training all the presentations and information received during the training are available for use by all experts from the directorate, colleagues and other stakeholders.

According to the Statutes of the BFSA, the tasks of the TQD are as follows:

1. To take part in the development of programs for initial training of new employees of the agency.
2. To co-ordinate training of the agency staff, organised by the European Commission, international organisations and third countries.

3. To co-ordinate reporting of training, the Directorate has created training registers which contain details on the training carried out, topics covered, trainers and trainees and session dates, etc.
4. To prepare programs, organise and co-ordinate training courses for the qualification of BFSA staff.
5. To maintain a database for: Qualification of BFSA staff at regional and national level; Universities and Institutes eligible to train employees of the agency; Professors and associate professors, lecturers, experts and specialists with appropriate qualifications to conduct training. Appropriate steps have been taken in order to achieve the licensing of a Professional Training Centre of the BFSA.
6. To plan in co-operation with the heads of all BFSA Directorates, precise criteria for the development of training programmes as well as criteria for analysing and reporting results. The criteria for identification of training needs will be defined on the same basis.

TQD summarises Annual plan for the training of officials from BFSA on animal health, food and feed safety, import controls and plant health with input from the regions. The plan for 2011 was approved by the Executive Director of BFSA.

All officials involved in food safety control are civil servants and licensed veterinarians. The official veterinarians performing food safety control according to Art. 9.1 and 2 of the Law on Veterinary Activities must also have three years of service in the field of food safety control and have been trained in food safety issues.

Officials responsible for the organisation and inspection of plant health controls must have agricultural university degrees, with specialisation in the field of plant protection.

Officials from the Feed Control Directorate (FeCD) who are responsible for official control on feedingstuffs, have completed their initial training in all the control systems linked to feed. The staff receive annual training in accordance with the requirements of Article 6 of Regulation (EC) No 882/2004. The staff that was transferred from the former NGFS have also passed subsequent training (2009 long-term programme for obtaining advanced knowledge on controlling HACCP-systems as well as practical training). The training programme which was in progress in 2011 is in line with the legislation covering the following sectors: Feed and Animal Feeding, TSE/feed ban, GMO and Residues/VMPs in accordance with the Annex II of Regulation (EC) No 882/2004.

Before the 2011 GFA, FVO audits indicated that in most cases regular training was in place, but the efficiency of this training was not appropriate. In sectors such as meat, milk and poultry the inspectors were not able to identify deficiencies that were identified by the FVO teams.

During the 2011 GFA, this aspect was revised and it was found that inspectors in Bulgaria attended various training sessions. The CA provided evidence of training undertaken during 2010 and 2011 which included specific training in the areas where deficiencies were identified. The subjects included poultry, meat and milk, animal welfare at slaughterhouses; post mortem inspection; compliance with the requirements on microbiological criteria and analysis of carcasses; efficiency and quality standards of official checks and inspections performed at each single stage of manufacturing, processing and distribution. Official staff based in the regions participated in this training. There had been improvements in the sectors of feed and animal welfare. Nevertheless, training was found insufficient in the area of laboratories and import controls (training was provided in certain areas such as checks for personal

consignments, CITES and feed. However, no training had been provided for import controls due to financial restrictions).

With the creation of the BFSA, training assessment started but it is planned to formalise it further in a near future.

As regards effectiveness of training, the CA indicated that at the end of each training course official veterinarians were obliged to pass an exam. Currently, the new Training Department is assessing new options to improve the system. Evidences of training needs being formally assessed could not be found. A database was being created containing information on skills/qualifications of staff, training institutes and qualified trainers. In addition, separate database of all trainings conducted at national level and under the BTSF programme is created.

The Internal Regulations of organization, coordination, analyses and evaluation of trainings of the employees in BFSA are established by Order RD 11-1355/ 28.10.2011 of the BFSA Executive Director and published on the BFSA's web site:

<http://babh.government.bg/uploads/File/Obuchenie/Vatreshni%20pravila%20za%20obuchenie%20na%20slujitelite%20na%20BABH.pdf>

Organisation and implementation of official controls

There is a structure for the organisation of a control system for food and feed safety, animal health, animal welfare and plant health in Bulgaria. There are documented procedures containing information and instructions for staff performing official controls.

The organisation and implementation of official controls within individual sectors is described in Part 2 of the country profile.

Registration / approval of food business establishments

Detailed information on registration and approval of food/feed business operators is given under chapters 2.2, 2.4 and 2.7 of the country profile.

The RFSD register the establishments for production, processing, storing and packing of raw materials and foodstuffs of animal and non-animal origin, as well as establishments for the wholesale trade in foodstuffs of animal and non-animal origin. The RFSD also registers retail outlets selling solely food of animal origin and non-animal origin. See the following link: <http://www.babh.government.bg/en/registers.html>

Prioritisation of official controls

Detailed information on risk prioritisation is given under respective control systems in part 2 of the country profile and in the MANCP.

Control activities, methods and techniques

Detailed information on control activities, methods and techniques used by competent authorities is given under the respective control systems in part 2 of the country profile.

Sampling and Laboratory analysis

Laboratories used for official control purposes are designated by the CAs for the respective sectors. The laboratories used for official controls belong to BFSA or the MH.

Laboratory activities are described under designation of competent authorities (section I above).

List of National Reference Laboratories

| Name of the Laboratory | Location | Organisation | Thematic area |
|---|----------|--------------|--|
| NRL for mycotoxins in foods of plant origin - CLCTC | Sofia | BFSA | Mycotoxins in foods of non-animal origin |
| NRL for single pesticide residue methods - CLCTC | Sofia | BFSA | Residues of pesticides in foods of non-animal origin, |
| NRL for pesticide residues in fruits and vegetables, including commodities with high water and high acid content - CLCTC | Sofia | BFSA | Residues of pesticides in foods of non-animal origin, |
| NRL "Milk and milk products" RFSO - Sofia | Sofia | BFSA | Total bacterial count - TBC, total somatic cells count - TSSC, inhibitors, physical and chemical testing of raw milk and other |
| NRL Salmonella, campylobacter and antimicrobial resistance; NDRVI | Sofia | BFSA | Products of animal origin and feed |
| NRL for marine biotoxins :NDRVI Sofia | Sofia | BFSA | Fish, molluscs and crustaceans |
| NRL for Listeria and Escherichia coli - NDRVI | Sofia | BFSA | Foodstuffs of animal origin |
| NRL Parasites (in particular Trichinella, Echinococcus and Anisakis) - within NDRVI in Sofia | Sofia | BFSA | Trichinella, Echinococcosis and Anisakis |
| NRL for residues of anabolic medicines and unauthorized substances in biological fluids, raw materials and food of animal origin (Group A(1), (2), (3), (4), (5) and (6) - CLVCE in Sofia | Sofia | BFSA | VMP residues and pollutants referred to in Directive 96/23/EC, biological fluids, raw materials and food of animal origin |
| NRL for residues of veterinary medicines in biological fluids, raw materials and food of animal origin (Group B (1), (2)(a), (b), (d), (e) and B (3)(e) to Directive 96/23/EU)- CLVCE in Sofia | Sofia | BFSA | VMP residues and pollutants referred to in Directive 996/23/EC, biological fluids, raw materials and food of animal origin |
| NRL for residues of environmental contaminants in raw materials and food of animal origin (B (2)(c), (3)(a), (3)(b), (3)(c) and (3)(d) to Directive 96/23/EU, CLVCE in Sofia | Sofia | BFSA | Materials and food of animal origin |
| NRL for residues of gamma-emitting radionuclides in water, beverages, feed, raw materials and food (B (3)(f) to Directive 96/23/EU); CLVCE in Sofia | Sofia | BFSA | Water, beverages, feed, raw materials and food |
| NRL for safety and quality of honey and bee products; CLVCE in Sofia | Sofia | BFSA | Honey and bee products; |
| NRL for TSEs within NDRVI in Sofia | Sofia | BFSA | Brains of animals to be tested for BSE and other TSEs |
| NRL "Animal proteins in feedingstuffs" within NDRVI " in Sofia | Sofia | BFSA | Feedingstuffs |
| NRL "Water content in poultry meat" NDRVI in Sofia | Sofia | BFSA | Poultry meat and other poultry products |
| NRL "Classical and African swine fever" NDRVI in Sofia | Sofia | BFSA | Diagnostic samples taken from animals to be tested for CSF and/or ASF |
| NRL for African horse sickness within NDRVI in Sofia | Sofia | BFSA | Diagnostic samples taken from equidae |
| NRL "Avian influenza and Newcastle disease" within NDRVI | Sofia | BFSA | Diagnostic samples taken from poultry and other birds |
| NRL "Foot-and-mouth disease and swine vesicular disease" | Sofia | BFSA | Diagnostic samples taken from cloven- |

| Name of the Laboratory | Location | Organisation | Thematic area |
|---|----------|--------------|---|
| within NDRVI | | | hoofed animals |
| NRL "Fish diseases, mollusc diseases and crustacean diseases"; within NDRVI | Sofia | BFSA | Diagnostic samples taken from fish and other marine organisms |
| NRL "Rabies and monitoring the effectiveness of rabies vaccination"; within NDRVI | Sofia | BFSA | Appropriate diagnostic samples taken from animals to be tested for rabies |
| NRL "Bluetongue" within NDRVI | Sofia | BFSA | Diagnostic samples taken from ruminants |
| NRL for Brucellosis in animals within NDRVI | Sofia | BFSA | Diagnostic samples taken from animals |
| NRL "Tuberculosis and Anthrax" within NDRVI | Sofia | BFSA | Diagnostic samples taken from animals |
| NRL for Enzootic bovine leucosis with NDRVI | Sofia | BFSA | Diagnostic samples taken from animals |
| NRL for Leptospirosis in animals within NDRVI | Sofia | BFSA | Diagnostic samples taken from animals |
| NRL for FCM | Sofia | MH, NCPHA | FCM |
| NRL for GM foods | Sofia | MH NCPHA | GM foods |

The NRLs also perform analyses as routine laboratories in the area of their competences.

The competent authorities were requested to submit a laboratory table for each NRL according to Regulation (EC) No 208/2011, which contained details in relation to its accreditation status, the number of European Reference Laboratory (EURL) proficiency tests in which they participated and information as regards the relevant routine laboratories. These tables were provided by the CAs. It was identified that in Bulgaria there is no designated NRL for the following sectors: additives for use in animal nutrition, for heavy metals in feed and food, Polycyclic Aromatic Hydrocarbons, zootechnics and equine diseases other than African horse sickness.

The audit team found during the 2011 GFA, that the Bulgarian laboratory network is in the process of rationalisation and consolidation. Improvements towards achieving compliance with Article 12 of regulation (EC) No 882/2004, designation of NRLs and increased participation in proficiency testing were identified. However, in a few areas, insufficient laboratory capacity and problems with accreditation of laboratories were still present (methods of analysis not included within the scope of accreditation, problems on implementation of quality assurance systems in already accredited laboratories, validation of methods, and insufficient participation in relevant comparative tests). In some areas, such difficulties were solved by means of contracting external laboratories, in particular in the area of Veterinary Medicine Residues (VMR). The 2011 Residues monitoring plan will be in conformity with Council Directive 96/23/EC if the testing of the missing substance groups is carried out in this laboratory.

Procedures for performance and reporting of control activities

All procedures are available and accessible on the respective websites, electronically and in hard copy.

Detailed information on procedures for performance and reporting of control activities are given in the respective sectors in part 2 of the country profile.

Transparency and confidentiality

Information on control activities (including programmes and results) and the relevant legislation is published on the individual competent authorities' websites.

The MANCP, the annual report, audit information and RASFF information are published on the MAF website.

MANCP:

<http://www.mzh.government.bg/MZH/bg/ShortLinks/ZJBH/zakon.aspx>

Audits:

<http://www.mzh.government.bg/MZH/bg/ShortLinks/ZJBH/Oditi.aspx>

The BFSA has its own website where they publish the names of the establishments closed down, outbreaks, press releases, etc.

www.babh.government.bg

The MH publishes the results of controls on the regional websites.

Enforcement measures

Measures in case of non-compliance

Measures taken in cases of non-compliance are described in the MANCP and also in the annual report under the relevant sectors of official controls.

According to the Bulgarian CAs, the official control on food is implemented by appropriate methods and techniques such as monitoring, surveillance, verification audit, inspection, sampling and analysis.

The Food Law establishes that official control of food is carried out under procedures in compliance with Regulation (EC) No 882/2004 and is implemented by appropriate methods and techniques. The Law describes the activities that constitute official controls.

In case of infringements for which prescriptions are already issued and fines and sanctions imposed, the producers and traders are obliged to pay a tax for the inspection and for controls on imported or exported food and food to be placed on the market.

In accordance with the Food law, in case of non-compliance the CAs have the right to:

1. Suspend the full or part operation of the food production and marketing establishment temporarily or permanently in case of infringements of the norms and requirements specified in legislation;
2. Carry out monitoring;
3. Stop the manufacturing of foodstuffs which directly or indirectly threaten the health of people and to order their return, withdrawal, destruction, reprocessing or use for other purposes;
4. Issue acts for established administrative infringements;
5. Restrict the access to the establishments under prohibition through certifying signs;

6. Restrict or prohibit placing on the market the foodstuffs;
7. Undertake the necessary actions ensuring the food safety and compliance with the normative requirements;

According to the Law on veterinary activities, on suspicion of deviation from the requirements of safety on raw materials and foods of animal origin or products, obtained from animal by-products (ABP), the official veterinarians:

1. Shall impose a written temporary ban and put under restriction the raw materials, foods of animal origin and their products, obtained from ABP, in a warehouse of the owner or their consignee;
2. Shall carry out inspections.

Depending on the type and extent of the breaches, indicated in the record or the report some of the following measures shall be taken:

1. Give binding instructions for removal of the breaches;
2. Ban of transportation, trade and placing on the market of raw materials and foods of animal origin and their products, obtained from ABP;
3. Instructions for processing or destruction of raw materials and foods of animal origin and products, obtained from ABP;
4. Ceasing of a part or the whole activity at the establishments.

Where the owner of the establishment had removed the breaches before the expiry of the prescribed period indicated in the prescription, he shall, in writing, inform the issuing veterinarian, and request him to carry out an inspection of the establishment.

Within 3 days of the expiry of the period for removal of the breaches, indicated in the prescription, the official veterinarian, who had issued it, shall carry out an inspection at the establishment and in cases where the breaches have been removed, shall reflect this in the prescription, by entering a date, signature and stamp.

Where the breaches have not been removed, after expiry of the indicated prescription period, the official veterinary shall within 3 days issue an order to stop that part or the whole activity at the establishment.

Measures shall be imposed independently or simultaneously by imposing an administrative penalty (Act for administrative infringement followed by punitive decree that is issued by the director of the RFSD).

The official veterinarians by imposing an order shall require the destruction of the raw materials, foods of animal origin, or ABP, obtained from them, where:

1. They find, that the materials or feed are unfit for consumption or dangerous to human and/or animal health;
2. They find, that the commodities are of unknown origin;
3. They find, that the commodities are imported in violation of requirements;
4. Official information is received indicating that these goods are dangerous to human and/or animal health;
5. They find, that the commodities are produced in sites which have been stopped from operating according to the order of the Law on veterinary activities or of the Law for Foodstuffs or in sites not registered according to the order of the Law for Foodstuffs.

The official veterinary shall draw up a record, wherein shall be described the type, the quantity, the number and other characteristics of the establishments, subjected to a destruction order. The record is an integral part of the order.

The losses from the imposed ban following non-compliance with the veterinary medical requirements shall be charged to owners of the establishments, subject to control.

The Law on veterinary activities contains lists of establishments where controls on animal health shall be carried out including units for production, processing and storage of raw materials and foods of animal origin.

The control on animal health shall also be carried out on the activities of the veterinarians, who have been registered for execution of a veterinary medical practice.

The animal health control shall be carried out through veterinary medical checks of the establishments and of the documentation; Clinical examinations, killing and autopsy of animals with a diagnostic purpose. Testing and sending of samples for laboratory examinations; Issuing of veterinary medical documents; Imposing of measures of prophylactics, limitation and eradication of the animal diseases and notifying of the interested parties and juridical persons; Imposing of compulsory administrative measures; conducting of epizootic study for detection of the reasons for the occurrence of the disease.

When the CAs identify breaches, depending on their type and severity, they shall undertake one or several of the following measures: give binding prescriptions, wherein deadlines for the elimination of the breaches shall be fixed; impose bans; order an eradication or a redirection for a thermal or a chemical re-processing of raw materials and foods of animal origin, ABPs and products, derived therefore, feed raw materials, feed additives and finished feedingstuffs.

The measures in case of non-compliance in the feed sector are performed in accordance with the requirements of Article 54 and 55 of Regulation No 882/2004. The penalties and sanctions are laid down in the Chapter - Administrative penal provisions of the Feed law.

When carrying out official controls and non-compliances are detected, the protocol to be drawn up should contain the infringements that have been detected. Short but reasonable deadline should be prescribed in order to correct the deficiencies. Within the deadline, a second, non-planned inspection is carried out. In cases where the prescription is not fulfilled, an administrative act is issued. Fines and sanctions for legal entities are higher than those for individual persons. An increase in the amount of the fine or sanction is foreseen when the non-compliance is repeated.

With regard to VMPs, according to Article 388, paragraph 1 of the Law on veterinary activities, the inspectors from the Control of VMPs directorate and the RFSDs shall check at any time the establishments for manufacturing, storage, sale and administration of veterinary medicinal products; shall demand and examine all documents, relevant to manufacturing and quality of veterinary medicinal products; shall issue prescriptions for the removal of detected breaches/inconsistencies; shall put a ban on veterinary medicinal products in the case of a suspicion of deviation in the quality indicators until the results of the laboratory tests have been received; and shall take samples;

According to Article 389, paragraph 1 of the Law on veterinary activities, when breaches are detected, inspectors from the BFSa shall issue instructions for their correction; stop temporarily the activity of part or the whole establishment, until the breaches have been corrected. According to Article 472, paragraph 1 of the same Law, measures for violations found shall be imposed by acts, drawn up by veterinaries of the BFSa according to the requirements of the Law on the administrative infringements and punishments.

Sanctions

The legal basis for imposition of administrative sanctions arises from the framework legislative acts. The framework legislation for food and feed safety controls comprises the Food Law (SG No 102/2003, last amended, SG No 8/2011); Veterinary Activity Law (SG No. 87/2005, last amended SG No 92/2011); Feed Law (SG No 55/2006, last amended SG No 8/2011) and the Plant Protection Law (SG No 91/1997, last amended SG No 28/2011) as mentioned above.

The following table includes the most common non-compliances of the existing legislation on food - Food Law and Law on Veterinary Activity and the sanctions imposed:

Sanctions and measures laid down in the legislation on food in case of the most common non-compliances

| Non-compliance | Legal base | Foreseen sanctions and measures |
|---|---|--|
| 1. Production or trade with food in an establishment, which is not registered under the Law on foodstuffs and the Law on veterinary activity. | <p>Law on the foodstuffs</p> <p>Art. 12. Production and trade of foodstuffs in the country shall be carried out only in establishments registered by the order of this law</p> <p>Law on the veterinary activity</p> <p>Art. 253. (1) Depending on the type and extent of the breaches, indicated in the record or the report some of the following measures shall be taken:</p> <p>3. Instruction for processing or destruction of raw materials and foods of animal origin and products, obtained from animal by-products;</p> | <p><u>Individual persons</u> shall be fined between 1500 BGL and 2000 BGL and for repeated commitment of the same offence - 2000 BGL to 4500 BGL.</p> <p>For violation committed by a <u>legal entity</u> the imposed sanction shall be from 2000 BGL to 4500 BGL and for repeated offence - from 4500 BGL to 6000 BGL.</p> <p>Directing for disposal of foodstuffs which come from non-registered establishments.</p> |
| 2. Placing on the market of foods without identification marking, indicating their origin | <p>Law on the veterinary activity</p> <p>Art. 58. (1) Raw materials and foods of animal origin intended for placing on the market shall be marked with a health or identification mark for identifying their origin.</p> | <p><u>Individual persons</u> shall be fined between 50 BGL and 150 BGL and for repeated commitment of the same offence - 150 BGL to 300 BGL.</p> <p>For violation committed by a <u>legal entity</u> the imposed sanction shall be from 500 BGL to 1000 BGL and for repeated offence - from 1000 BGL to 3000 BGL.</p> |
| 3. Missing label, irregular or incomplete labelling | <p>Law on the foodstuffs, Ordinance on the requirements for labelling and presentation of foods</p> <p>Art. 9. (1) The producers and the sellers of foodstuffs shall be obliged to offer to the consumers in the country foodstuffs labelled in Bulgarian language. It shall be allowed the data on the labels to be presented in other languages together with Bulgarian.</p> <p>Law on the veterinary activity</p> <p>Art. 248. The persons, carrying out production, transportation, trade and placing on the market of raw materials and foods of</p> | <p>Individual persons shall be fined between 250 BGL and 500 BGL and for repeated commitment of the same offence - 500 BGL to 1000 BGL.</p> <p>For violation committed by a legal entity the imposed sanction shall be from 500 BGL to 1000 BGL and for repeated offence - from 1000 BGL to 3000 BGL.</p> <p>Individual persons shall be fined between 500 BGL and 1000 BGL and for repeated commitment of the same offence - 1000 BGL to 2000 BGL.</p> <p>For violation committed by a legal entity the</p> |

| Non-compliance | Legal base | Foreseen sanctions and measures |
|---|--|---|
| | animal origin: 3. Shall mark with an identification marking and label. | imposed sanction shall be from 2000 BGL to 5000 BGL and for repeated offence - from 5000 BGL to 10000 BGL. |
| 4. Placing on the market of foods, unfit for human consumption | <p>Law on the foodstuffs</p> <p>Art. 20. (1) Placing on the market of foodstuffs shall not be permitted if it:</p> <p>3. is unfit for consumption by people.</p> <p>Law on the veterinary activity</p> <p>Art. 253. (1) Depending on the type and extent of the breaches, indicated in the record or the report some of the following measures shall be taken:</p> <p>3. Instruction for processing or destruction of raw materials and foods of animal origin and products, obtained from animal by-products;</p> | <p>Individual persons shall be fined between 1000 BGL and 2000 BGL and for repeated commitment of the same offence - 2000 BGL to 4000 BGL.</p> <p>For violation committed by a legal entity the imposed sanction shall be from 2000 BGL to 4000 BGL and for repeated offence - from 4000 BGL to 6000 BGL.</p> <p>Directing for disposal of foodstuffs which come from non-registered establishments.</p> |
| 5. Non-compliance with the temperature conditions for storage | <p>Ordinance No 5 on the hygiene of foods</p> <p>Art. 60. (1) The raw materials, food ingredients, intermediate and finished products, which are a favourable environment for multiplication of pathogens or for production of their toxins, shall be kept under temperature conditions , which do not allow public health risks.</p> | <p>Individual persons shall be fined between 500 BGL and 1000 BGL and for repeated commitment of the same offence - 1000 BGL to 2000 BGL.</p> <p>For violation committed by a legal entity the imposed sanction shall be from 1000 BGL to 2000 BGL and for repeated offence - from 2000 BGL to 4000 BGL.</p> |
| 6. Non-satisfactory hygiene conditions of an establishment for production or trade. | <p>Ordinance No 5 on the hygiene of foods</p> <p>Art. 12. The establishments for production and trade of foods and their surroundings shall be kept clean and in good condition.</p> | <p>Individual persons shall be fined between 500 BGL and 1000 BGL and for repeated commitment of the same offence - 1000 BGL to 2000 BGL.</p> <p>For violation committed by a legal entity the imposed sanction shall be from 500 BGL to 1000 BGL and for repeated offence - from 1000 BGL to 3000 BGL.</p> |
| 7. Non-fulfilment of the prescription or of an order of the official control | <p>Law on the foodstuffs</p> <p>Art. 31. (1) The persons who manufacture and trade foodstuffs shall be obliged:</p> <p>1. to fulfil the prescriptions of the competent bodies;</p> <p>Law on the veterinary activity</p> <p>Art. 248. The persons, carrying out production, transportation, trade and placing on the market of raw materials and foods of</p> | <p>Individual persons shall be fined between 250 BGL and 500 BGL and for repeated commitment of the same offence - 500 BGL to 1500 BGL.</p> <p>For violation committed by a legal entity the imposed sanction shall be from 500 BGL to 1500 BGL and for repeated offence - from 1500 BGL to 3000 BGL.</p> <p>Individual persons shall be fined between 200 BGL and 1000 BGL and for repeated commitment of the same offence - 400 BGL to 2000 BGL.</p> <p>For violation committed by a legal entity the</p> |

| Non-compliance | Legal base | Foreseen sanctions and measures |
|--|---|--|
| | animal origin : 13. Shall undertake the issued instructions and the imposed bans of the veterinarians. | imposed sanction shall be from 1000 BGL to 3000 BGL and for repeated offence - from 3000 BGL to 10000 BGL. |
| 8. Multiple non-compliances with regard to the hygiene conditions of the establishment and lack of control on the CCP, which pose risk for the safety of the produced products | <p style="text-align: center;">Law on the veterinary activity</p> Art. 253. (1) Depending on the type and extent of the breaches, indicated in the record or the report some of the following measures shall be taken: 4. Ceasing of part or the whole activity at the establishments under Art. 221; | Order for ceasing of the activity of the establishment |

Official control on feed - undertaken measures and imposed sanctions

| Measure | Type of the operator in the feed sector | Total BGLs | Remarks |
|---|---|------------|--|
| Applied art.14 of Regulation (EO) № 183/2005 – temporary suspension of registration or approval | Registered producers of compound feedingstuffs | - | - |
| | Approved producers of compound feedingstuffs | - | - |
| | Producers of feed materials | - | - |
| | Registered traders of compound feedingstuffs and feed materials | - | - |
| Applied art.15 of Regulation (EO) № 183/2005 – withdrawal of registration or approval | Registered producers of compound feedingstuffs | - | - |
| | Approved producers of compound feedingstuffs | - | - |
| | Producers of feed materials | - | - |
| | Transport operators | - | - |
| | Registered traders of compound feedingstuffs and feed materials | - | - |
| | Approved traders of feed additives and premixes on the bases of additives | - | - |
| Imposed prohibitions on feeds | Approved producers of premises on the basis of additives | - | - |
| | Registered producers of compound feedingstuffs | - | - |
| | Approved producers of compound feedingstuffs | - | - |
| | Non-registered producers of compound feedingstuffs | - | - |
| | Producers of feed materials | - | - |
| | Registered traders of compound feeds and feed materials | - | - |
| | Non-registered traders of compound feedingstuffs and feed materials | - | - |
| | Farms in accordance with Annex 1 and 3 of Regulation (EC) № 183/2005 | - | - |
| Administrative infringement acts issued | Non-approved traders of additives and premixes on the basis of additives | 10 000 | Not-approved in accordance with art. 10 of Regulation (EC) № 183/2005 |
| | Registered traders of compound feeds and feed materials | x 500 | Non-compliances with labelling in accordance with Regulation (EC) № 767/2009 |
| | Non-registered individual trader of compound feeds | 1000 | Non-registered in accordance with art. 9 of Regulation (EC) 183/2005 |
| | Non-registered legal entities, trading with compound feeds | x 3000 | Non-registered in accordance with art. 9 of Regulation (EC) 183/2005 |
| | Non-registered legal entity, producing compound feeds | x 3000 | Non-registered in accordance with art. 9 of Regulation (EC) 183/2005 |

Data from March to end of August 2011 on enforcement was provided to the audit team during the 2011 GFA. This data included the following details: name of the operator, details on the type of measure imposed (temporary suspension, withdrawn of approval, prohibition on transport and use of feedingstuffs and administrative sanctions including the amounts of the fines) and number of measures imposed. It was found, however, that in the area of animal welfare few sanctions were imposed and they were not sufficiently dissuasive. There is a system of monthly and quarterly reporting which includes infringements and corrective measure imposed.

Sanctions could vary between 3000-5000 BGN on average. The maximum for major non-compliances could reach 50,000 BGN.

2011 Official controls - undertaken measures and imposed sanctions

| Sector | Total number of inspections | Total number of the prescriptive documents | Total number of administrative infringement acts (financial sanctions) | Total number of punitive decrees | Fines in BGL | Total number of closed establishments (not applicable for all sectors) |
|---|-----------------------------|--|--|----------------------------------|--------------|--|
| 1. Food (milk) establishments | 5 450 | 460 | 34 | 33 | 20 590 | 5 |
| 2. Food (meat) establishments | 13 001 | 592 | 98 | 86 | 67 680 | 3 |
| 3. Food (non animal origin) establishments | 12 986 | 2 574 | 468 | 410 | 177 550 | 261 |
| 4. Trade network (markets, supermarkets etc.) and restaurants)(food of animal and non-animal origin | 94 840 | 9 710 | 3 276 | 3 064 | 1 319 143 | 443 |
| 5. Warehouses - food of animal and non-animal origin | 6 877 | 795 | 99 | 95 | 50 850 | 32 |
| 6. Animal welfare during slaughter | 11 303 | 1 | 3 | 0 | 0 | 0 |
| 7. ABP establishments | 884 | 29 | 1 | 1 | 500 | 0 |
| 8. Animal welfare – at reception in slaughterhouses for red meat and poultry and lagomorphs meat “white meat” | 11 898 | 16 | 30 | 30 | 3 900 | 0 |
| 9. Animal welfare: transport | | | | | | |
| <i>During transport</i> | 115 | 9 | 84 | 78 | 10 640 | |
| <i>At the place of destination</i> | 3 353 | 14 | 5 | 5 | 300 | |
| <i>At markets</i> | 25 | 4 | 10 | 10 | 1 100 | |
| <i>At place of departure</i> | 597 | 6 | 1 | 1 | 100 | |
| <i>At staging points</i> | 2 | 0 | 0 | 0 | 0 | |
| <i>At assembly centres</i> | 145 | 2 | 0 | 0 | 0 | |

| | | | | | | |
|---|---|-----|----|----|---|---|
| 10. Animal welfare – at farm | | | | | | |
| <i>Laying hens</i> | 141 | 24 | 6 | 5 | 3 550 | |
| <i>Broilers</i> | 112 | 7 | 0 | 0 | 0 | |
| <i>Pigs</i> | 339 | 51 | 0 | 0 | 0 | |
| <i>Calves</i> | 342 | 32 | 0 | 0 | 0 | |
| <i>Other farm animals</i> | 1 876 | 176 | 35 | 35 | 2 810 | |
| 11. Feed | 1065 (in accordance with the annual plan), 195 (subsequent) | 653 | 10 | 10 | In accordance with the Feed Law, the average amount of fines and sanctions is between 3000 – 5 000 BGL, and the maximum – 50 000 BGL. (Imposed with punitive decrees in 2011 amounted to 25 000 BGL. | 46 |
| 12. VMPs | 1671 | 457 | 54 | 46 | 17 900 | 1 withdrawn licence for manufacture of VMP; 1 temporary suspension of VMP manufacture; 1 withdrawn licence for retail trade of VMP. |
| 13. Control on plant protection products on the market | 1481 | 362 | 44 | 20 | No information available | |
| 14. Control on the use of plant protection products | 2325 | 759 | 8 | 7 | No information available | |
| 15. Plant health | 2438 | 46 | 2 | 2 | 1200 | 0 |
| 16. Quality control and safety of fresh fruits and vegetables | 16758 | 620 | 20 | 12 | 13 200 | 0 |

Verification and review of official controls and procedures

Verification procedures

The procedures for monitoring and supervision of the implementation of the policies within the direct chain of command as well as verification of the performance are described in Part 2 of the country profile within the individual control systems. The processes cover all levels of control administration including central, regional and local.

In accordance with the annual program for performance of official controls, developed on the basis of the instruction on the implementation of the MANCP for the control on raw materials and foods, food additives and food contact materials, the heads of FC Departments within the RFSD are performing periodical checks of the activities of the inspectors as regards:

1. Their abilities to use the methods for official control, defined in Regulation (EC) No 854/2004 and 882/2004
2. Their abilities to undertake adequate measures in accordance with the Law on foodstuffs and the Law on veterinary activity and their abilities to record all the required documentation
3. Their abilities to find non-compliances with regard to the fulfilment of the requirements in the legal acts.

With regard to animal health, in accordance with the requirements of Regulation 882/2004, a check-list was designed; model AHWD 148, approved by an order 11-30/08.03.2011 of the Executive Director of the BFSA on the effectiveness of the official control on animal health.

Twice a year the heads of Animal Health Departments within the RFSD perform controls on the effectiveness of the official control on animal health. The above-mentioned check-list is completed with the relevant findings. Recommendations with deadlines for their correction are also included.

With regard to the feed sector, due to the fact that at regional level the officials responsible for the control on feed are appointed mainly in the Animal Health Departments, there is not enough verification controls performed by the heads of units. Therefore there is a system in place implemented by officials of FeCD at central level.

There is a plan, drawn up for the abovementioned issue. The control is performed through a visit to the relevant regional directorate. During this visit a documentary check is carried out, as well as joint checks in establishments in the feeding sector with the participation of the expert or the inspector, responsible for control on feed. This approach is used also for practical training of the inspectors and the experts at regional level. The shortcomings in the performance of the inspectors, found at these visits are taken into account when planning the topics for the following training sessions.

As a general verification procedure within the BFSA there is the “Co-ordination and Control” Directorate (CCD) that carries out checks, inspections and mainly audits of Regional Food Safety Directorates (RFSD) in accordance with its competence and in case of infringement or non compliances to makes proposals and measures to be enacted /entered into effect by an Order signed by BFSA Executive Director, in order to ensure the elimination of the non-compliances identified within these audits.

These audits (called also in Bulgarian “complex checks”) are usually performed under an annual control plan approved by BFSA ED, including their detailed schedule per each calendar year. Complex checks (the Audits) are performed by case-by-case designated expert groups (called in “commissions” in Bulgarian), which are designated under special BFSA ED’s Order and including experts of all BFSA control areas (animal health and welfare, feed controls, foodstuffs controls, VMPs’ controls, plant protection, legal affairs, financial and other economic activities, laboratory and testing activities, border control activities).

Within the period between 01.01.2011 and 30.04.2012, the CCD has organized and performed a total of nine (9) “complex checks”, audits in the following RFSD of Veliko Tarnovo, Vratsa, Sliven, Targovishte, Yambol, Dobrich, Sofia-town, Kyustendil, Blagoevgrad.

In lieu with the non-compliances and/or omissions in exercising official controls that have been identified within these audits and recorded in the Reports thereon, and based on specific expert opinion(s) and recommendations delivered by the CCD, there are some disciplinary cases initiated and disciplinary sanctions imposed on the following BFSA officials and/or employees.

Based on notifications about non-compliant or illegal actions or activities or due to lack of control subject to exercising by certain RFSD official(s), the CCD is obliged to undertake the so called thematic (on-subject) checks, in order to validate the confirmation or denial of these ‘signals’. Based on such checks and under the CCD specific proposal, there have been disciplinary cases initiated against 13 BFSA officers or officials.

The normal practice is that the Order to designate the expert group to perform an audit would specify also the deadline for developing a detailed “audit report” including evidences and specific recommendations for improving the activity of the RFSD subjected to auditing. A copy of this audit report would be forwarded to the Director of RFSD subjected to auditing, the latter been obliged to present her/his report on the measures and actions foreseen, in order to ensure elimination or correction of the non-compliances identified in the Audit Report.

The experts from CCD work in close co-operation with the officials from the Ministry of Interior, the Commission for consumer protection, NGOs for animals welfare and all structural and territorial subdivisions of BFSA to achieve optimum results in the performance of control activities and imposition of prompt and adequate measures in case of detection of non compliant actions, posing a risk to animal health and consumers.

During FVO audits, it was found that inspectors were not identifying all deficiencies during their official controls. This aspect was checked during the 2011 GFA for this reason. During the GFA the audit team noted that a comprehensive system of verification of effectiveness of official controls had been put in place and evidence of this system was analysed. Nevertheless, to ascertain if this system is fully implemented and it is effective would require further assessment during future FVO audits and GFAs. Results on verification activities carried out by the CAs will need to be assessed.

Audit

The BFSA has been implementing a system for conducting internal audits in accordance with the requirements of Art. 4 (6) of Regulation (EC) № 882/2004. In accordance with Art. 25 of Code of organization of BFSA, adopted by Council of Ministers Decree № 35 of 14.02.2011, published in SG № 15 of 18.02.2011 as an audit body that plans, organizes, carries out and documents internal audits is indicated by “Quality management” Directorate (QMD), part of the Central Office of BFSA.

According to the Code of organization of BFSA, QMD has the following functions:

- Planning, organizing, carrying out and documenting audits (Obtaining and Documenting Audit Evidence) of official controls, implemented by the BFSA in accordance with Art. 4, item 6 of Regulation № 882/2004 of the European parliament and the Council of 29.04.2004 concerning the official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules.
- Developing, maintaining and observing the documented procedures for Audit planning and execution, follow up audits and managing an Audit.
- Drawing up draft orders, procedures and other documents related to its activity.

The overall process of audits of official controls (planning, organizing, implementing, documenting and follow-up Audits) is based on the principles and rules laid down in Commission Decision 2006/677/EC creating guidelines that define the criteria for carrying out the audits under Regulation (EC) № 882/2004 and BS EN ISO 19011/2005 “Guidelines for conducting an audit of management systems and environmental quality systems”.

Members of the Audit team are selected for each audit and approved by order of Executive Director of BFSA. They are highly qualified experts in their field, trained and certified to IEC EN ISO 19011/2004.

In 2011 and 2012 under the program of European Commission, DG Health and Consumers- Better training for safer food (BTSF) experts from QMD have obtained certificates for their participation in training courses –“Setting up and implementation of an audit system”.

All the documents related to the Internal Audit system are published on the website of BFSA on the following email addresses:

<http://www.babh.government.bg/bg/actualno-department-qa.html>

<http://www.babh.government.bg/bg/examples-qa.html>

In the internal audit program for 2011, 10 audits were planned covering the following topics:

- Evaluation of the overall activities of “Control of VMPs” Directorate (CVMPD), according to the Code of organization of BFSA
- To check whether official controls on feed and food law, animal health and animal welfare, usage and placing on the market of plant protection products is conducted under the provisions of Regulation (EC) № 882/2004.
- Evaluation on the level of compliance of documentation in the field of Phytosanitary control under the methodological guidance for implementing Ordinance № 1 of 27.08.1998 on the Phytosanitary control, Ordinance № 68 of 16.05.2006 for Phytosanitary inspections of imports from third countries of plants and plant products performed in places other than specified for introduction into the European Community and the legal basis related to Phytosanitary control, Directive 2000/29, control directives and Commission decisions.
- Evaluation of the official controls system on use and placing on the market plant protection products.
- Evaluation of the official controls system for controlling the production and trade of raw cow’s milk and dairy products.
- Evaluation of the official controls system in the field of food labeling.

- Evaluation of the official controls system for controlling imports of food of animal origin.
- Evaluation of the official controls system for controlling imports of food of animal and non animal origin, import and transit of live animals.
- Evaluation of the official controls system in the field of food additives.
- Evaluation of the official controls system for controlling the production and placing on the market of fishery products.

The last issue that was scheduled for audit in November 2011 due to lack of funds was postponed and included in the Audit program for 2013. Outside the annual program the audit with scope “Determination of the compliance with embedded test methods and management system in the laboratory with BS EN ISO / IEC 17025:2006” was conducted.

The audit program for 2011 covered one department on central level “Control of veterinary medicinal products” and 10 regional directorates (Regional food safety directorates) RFSD-Veliko Tarnovo, RFSD-Pzardhjik, RFSD- Smolyan, RFSD- Burgas, RFSD Plovdiv, RFSD Lovech, RFSD-Pleven, RFSD Blagoevgrad, RFSD Haskovo, RFSD Sofia city. The audits carried out examined the effectiveness of official controls on site as followed:

- One pig farm and two dairy farms.
- 8 milk processing enterprises and 4 dairy farms with storage facilities for milk.
- 8 meat processing enterprises, a slaughterhouse and 2 pig farms.
- 4 enterprises for production of bakery and 4 pastry enterprises.
- 4 production enterprises for soft drinks.
- One enterprise for production of additives and two warehouses for wholesale trade of food additives.
- Production sites for repackaging and 4 warehouses for storage of goods for wholesale and retail marketing of plant protection products (PPP).
- Three farmers of plants and plant products intended for food and feed
- Documentation files for compliance in the field of Phytosanitary control.

For all identified findings during the audit, audited organizations have drawn up action plans for corrective and preventive measures to remove them in specific terms. Action plans of the audited organizations are posted on the website of BFSA.

Animal Health and Food safety Directorate (AHFSD)

Experts from Animal Health and Food safety Directorate within MAF participate in activities on performance of audit of the official control carried out by the Bulgarian Food Safety Agency according to art. 4 (6) of Regulation № 882/2004. A team of 9 auditors has been trained to IEC EN ISO19011:2004 and IEC EN ISO 9001:2008 standards. The audit team is multidisciplinary. Auditors participated in training courses organised by the European Commission's BTSF program.

Participation of experts from AHFSD in joint audits is in accordance with the Procedure and audit programme, approved by the Executive Director of BFSA. Auditors from AHFSD within MAF have been appointed by Order № RD 09-688 of 4 May 2012 of the Minister of Agriculture and Food and have been included in the list approved by the Executive Director of BFSA.

Three audits were performed on the NVS, NGFS and NSPP at central level in 2007. Five audits were performed on the RVS, Territorial Units of NGFS and RSPP in 2008; 12

audits on the RVS, Territorial Units of NGFS and RSPP in 2009; 13 audits on the RVS, Territorial Units of NGFS and RSPP in 2010. Audits were performed in accordance with a Procedure approved by the Director of the AHFS Directorate in 2010 and audit Programme for 2010 approved by the Minister of Agriculture and Food.

Five audits were planned and performed in 2011 of the competent authorities carrying official control in Regional food safety Directorates Lovech, Montana, Dobrich, Varna and Shumen. Audits were performed in accordance with a Procedure approved by the Director of the AHFS Directorate in 2011 and audit Programme for 2011 approved by the Minister of Agriculture and Food.

40 recommendations concerning the non-compliances found were made during these audits, as follows by sectors:

- Food sector - 8 recommendations;
- Feed sector - 19 recommendations;
- Animal welfare - 4 recommendations;
- On the implementation of the measures in accordance with Plant Protection Law - 9 recommendations.

Following the audits, the audit team makes a Report which is sent to the audited organization by e-mail for comments on the factual content and the recommendations given. Within 5 working days the audited organization submits comments on the draft Report as well as information concerning the planned and taken measures including deadlines for their implementations for removal of non-compliances.

The AHFS is the National Contact Point (NCP) for the RASFF and also performs audit on the activities of the contact points within MAF. Three audits in the veterinary public health departments of the RVS were carried out in 2009, 7 audits in 2010.

Five audits were performed of the RASFF Competent Contact Points in Regional food safety Directorates Lovech, Montana, Dobrich, Varna and Shumen in 2011.

Multi-annual National Control Plan (MANCP)

The MANCP has been developed for the period of 2008-2010. A working group to prepare and oversee the implementation of the plan has been established and consists of representatives of all CAs chaired by a representative of the AHFSD within MAF. The plan is structured vertically according to the CAs involved in official controls and was prepared in accordance with Commission Decision 2007/363/EC. The implementation of the plan is carried out through documented procedures. In some sectors, a detailed methodology for prioritisation of official controls based on risk categorisation is established and applied. The MANCP has been amended and prolonged to the end of 2011 in order to ensure the effective starting and functioning of BFSA from the beginning of 2011.

A working group, chaired by AHFSD within MAF, was established by an Order of the Minister of Agriculture and Food (RD 09-649/10.08.2011) for the preparation of a new MANCP for the period January 2012 – December 2014. The new MANCP is published on the website of the Ministry of agriculture and food:

<http://www.mzh.government.bg/MZH/bg/ShortLinks/ZJBH/zakon.aspx>

The 2010 annual report on the implementation of the Multi Annual National Control Plan was provided to the Commission in July 2011 and is published on the [Ministry of Agriculture and Food website](#).

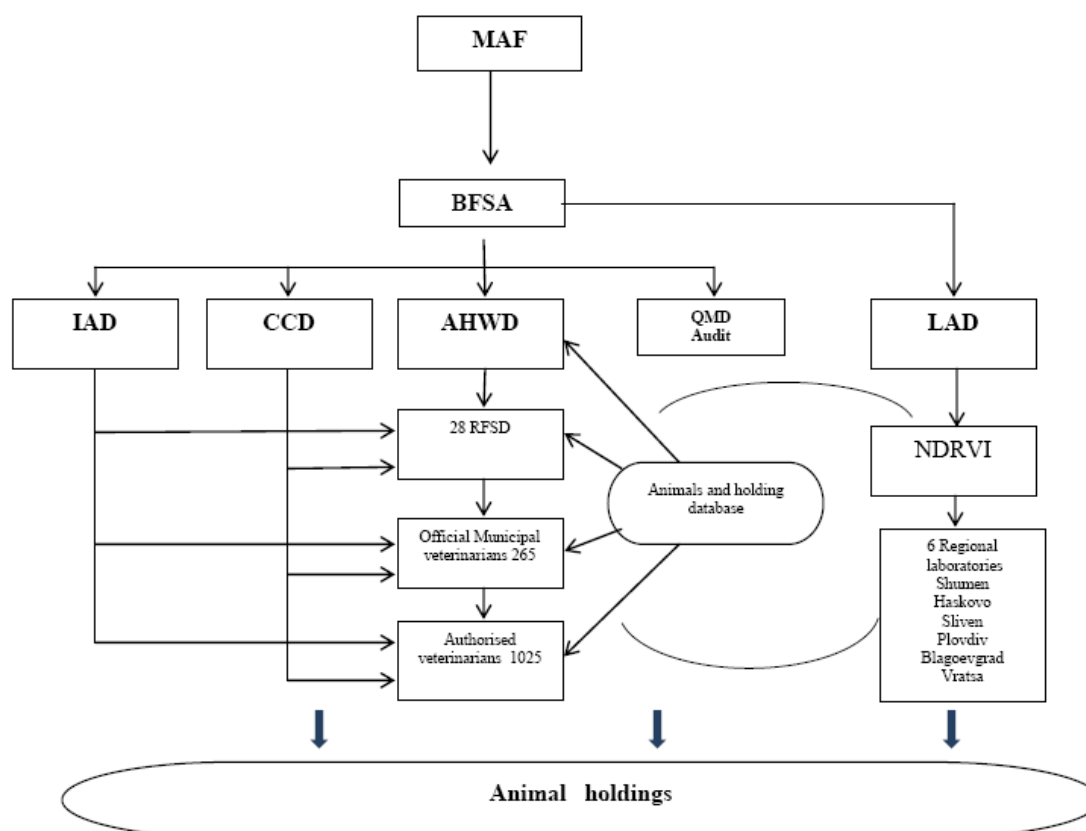
The following chart gives an overview of the distribution of responsibilities in relation to control systems and operational levels.

| Sector | Policy co-ordination | Co-ordination of controls | Implementation of controls | Laboratories | Risk assessment/ scientific advice |
|--|-------------------------|-------------------------------|----------------------------|---|------------------------------------|
| Animal Health | MAF (AHFSD) | BFSA (AHWD) | RFSD | NDRVI (TL Stara Zagora and TL V Turnovo), RFSD - Vratsa, Blagoevgrad, Shumen, Varna, Sliven, Haskovo, Plovdiv | RAC |
| Food of Animal Origin | MAF (AHFSD) | BFSA (FCD) | RFSD | NDRVI, CLVCE, RFSD - Vratsa, Blagoevgrad, Shumen, Varna, Sliven, Haskovo, Plovdiv, Gabrovo, Sofia-town | RFSD |
| Food post primary/retail | MAF (AHFSD) | BFSA (FCD) | RFSD | NDRVI, CLVCE, RFSD - Vratsa, Blagoevgrad, Shumen, Varna, Sliven, Haskovo, Plovdiv, Gabrovo, Sofia-town | RAC |
| Imports of animal and food of animal origin | MAF (AHFSD) | BFSA (BCD) | BIPs | NDRVI, CLVCE RFSD- Vratsa, Blagoevgrad, Shumen, Varna, Sliven, Haskovo, Plovdiv, Gabrovo, Sofia-town | RAC |
| Feedingstuff – quality and safety aspects | MAF (AHFSD) | BFSA (FCD) | RFSD | NDRVI CLVCE , LQGGPF | NDRVI, RAC |
| Imports/exports and transit of any kinds of feed materials and feedingstuffs | | | BIPs | NDRVI | |
| Feedingstuffs: primary agricultural production of plant origin, intended for feed. | MAF (AHFSD) | BFSA (BCD) | BIPs | NDRVI | RAC |
| Primary producers mixing feedingstuffs for their own needs without using additives and premixtures | MAF (AHFSD) | BFSA (FeCD) | RFSD | CLCTC | RAC |
| TSEs/ABP | MAF (AHFSD) | BFSA (AHWD) | RFSD AV | NDRVI | RAC |
| Veterinary medicines and residues | MAF (AHFSD) | BFSA (CVMPD) | CVMPD RFSD BIPs | NDRVI, CLVCE | RAC |
| Foodstuffs and Food hygiene | MAF (AHFSD) MH (PHD) | BFSA (FCD ¹) * | RFSD RHI | RFSD NDRVI, RHI | RFSD RAC |
| Imports of food of plant origin | MAF (AHFSD) | BFSA (BCD) | RFSD Customs | CLCTC, CLVCE, RHI-Pleven | RAC |
| Plant protection products and residues | MAF (AHFSD) | BFSA (PPFED) | RFSD | CLCTC | RAC |
| Animal Welfare | MAF (AHFSD) | BFSA (AHWD) | RFSD, BIPs, AV | NDRVI | RAC |
| Plant Health | MAF (AHFSD) | BFSA (PPQCSFFVD) | RFSD | CLPQ | RAC |

¹ With the exception of the official controls on bottled natural mineral, spring and table waters.

2. COMPETENT AUTHORITIES AND DISTRIBUTION OF RESPONSIBILITIES IN RELATION TO INDIVIDUAL CONTROL SYSTEM

2.1 Control system for animal health



| | |
|-------|---|
| BFSA | Bulgarian Food Safety Agency |
| RFSD | Regional Food Safety Directorate |
| AHWD | Animal Health and Welfare Directorate |
| LAD | Laboratory activities Directorate |
| CCD | Control and Coordination Directorate |
| IAD | Internal Audit Directorate |
| QMD | Quality management Directorate |
| NDRVI | National Diagnostic and Research Veterinary Institute |
| RL | Regional Laboratories |

Competent authorities

The central competent authority for animal health is the BFSA.

The AHWD of the BFSA is responsible for harmonisation and drafting legal documents relevant to its competencies. It also arranges for veterinary preventive measures against infectious and parasitic diseases including zoonoses and prepares the annual prophylactic, monitoring and eradication programmes. It is also responsible for the preparation of contingency plans, guidelines and instructions for the RFSD on the implementing of animal health measures.

The total number of staff involved in the animal health sector in the official services in Bulgaria is: 18 BFSA, 28 RFSD, 160 veterinary auxiliaries, 265 OMV (official municipal veterinarians).

Furthermore, 1,025 authorised private veterinarians (APV) perform official tasks under the animal health programmes.

Holding registration, animal identification and movement controls

Animal holdings keeping cattle, pigs, sheep and goats are registered on the Central Database (CDB) and a unique holding number is allocated to each holding. The CDB (World Vet system) is an Internet based system designed for multi-species functionality. The DAHW is responsible for overall management of the CDB. In the CDB data is entered by 1,400 users, including private veterinarians, veterinarians performing official controls on holdings, slaughterhouses, collection centres and others.

The national system of identification and registration of animals requires identification of all species by an individual number. The APV are responsible for tagging and registering the animals and providing monthly data to the OMVs who enter it into the CDB. A new module of the CDB was developed and entered into force.

The system for animal movement control is based on animal health movement certificates issued by the AV responsible for the farm. Passports are issued for large ruminants and equines. All holdings are required to keep holding registers and each change to the herd is entered in a record book.

The system for registration of livestock vehicles and hauliers has been developed in accordance with the requirements of Council Regulation 1/2005/EC. The national registers of the approved vehicles for short and long journeys are published on the web site of the BFSA (<http://www.babh.government.bg/en/registers.html>).

Animal health controls

Control measures (sampling, testing, and vaccination) prepared by the AHWD and approved by the MAF, are implemented by the RFSD, OMV and APV. There is an animal health department in each of the 28 RFSD. At local/district level, there are 265 municipalities each supported by an OMV who supervises the performance of the AV. A total of 1,025 APV carry out prophylactic and monitoring of the animal health programmes.

The APV report the results of their work on a monthly basis to the relevant OMV who summarises the input from all APVs and report to the RFSD. The RFSD reports to the DAHW on the implementation of the animal health programmes in their region on a monthly basis.

Specific eradication and monitoring programmes are approved for Bluetongue, Classical CSF in East Balkan pigs, CSF in relation to vaccination (serological testing), CSF in wild boars, Foot and Mouth Disease (FMD) (at the border with Turkey), Equine Viral Arthritis (EVA), Horse Influenza and African Horse Fever, TSE and some fish diseases. The programmes for 2011 are approved with Commission Decision 2010/712/EU, approving annual and multiannual programmes and the financial contribution from the Union for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2011 and following years.

The CCD performs audits at all administrative levels (DAHW, RFSD, OMV and APV).

The following table gives an overview of the outbreaks of animal disease in Bulgaria. More detailed information about the diseases notified by Bulgaria can be accessed at www.oie.int.

| Disease | Outbreaks |
|-------------|--|
| FMD | 1996 – 1 outbreak 2011- 11 outbreaks |
| CSF | 2000 – 1 outbreak 2001 – 1 outbreak 2002 – 32 outbreaks 2003 – 11 outbreaks 2004 – 4 outbreaks 2005 – 5 outbreaks in wild 2006 – 1 outbreak 2007 – 3 outbreaks 2008 – 1 outbreak 2009 – 4 outbreaks in wild |
| Blue-tongue | First outbreak 1999 2001 – 1 outbreak |
| Rabies | 1977 first reported cases in foxes 2001 – 61 outbreaks in wild 2002 – 15 outbreaks in wild 2003 – 17 outbreaks in wild 2004 – 10 outbreaks in wild 2005 – 10 outbreaks in wild 2006 – 1 outbreak in wild 2007 – 37 outbreaks 2008 – 47 outbreaks 2009 – 40 outbreaks 2010- 6 cases 2011- 1 case |

Source: MAF and OIE, BFSA

Contingency plans

At the end of 2009 the expert group at AHWD drafted an update of the contingency plan for emergency diseases in Republic of Bulgaria.

For practical purposes the BFSA has based its overall contingency plan on three major types:

- A Strategy and Resource plan,
- Operational manuals
- Instructions for practical matters during outbreak management.

The contingency plan for emergency diseases in Bulgaria (the strategy and resource plan, the operation manuals of the animal diseases and the practical instructions) is prepared in accordance with the requirements of national and European legislation, the OIE standards and characteristics of different diseases.

The documents are published on the web site of the BFSA: http://babh.government.bg/bg/actualno-department-health&article_id=108.html

Laboratories

The NDRVI in Sofia is a specialised body of the BFSA on diagnostics and research activities in the field of animal health.

The NDRVI's reference activities are organised within eighteen (18) NRLs that have been designated as such by an Order signed by the Minister of Agriculture and Food and structurally organised within two 'National Reference Centres', which are the 'National Reference Centre on Safety of Foodstuffs (16.01.2012 last modified) and the 'National Reference Centre on Animal Health' and another two 'Testing Laboratories'.

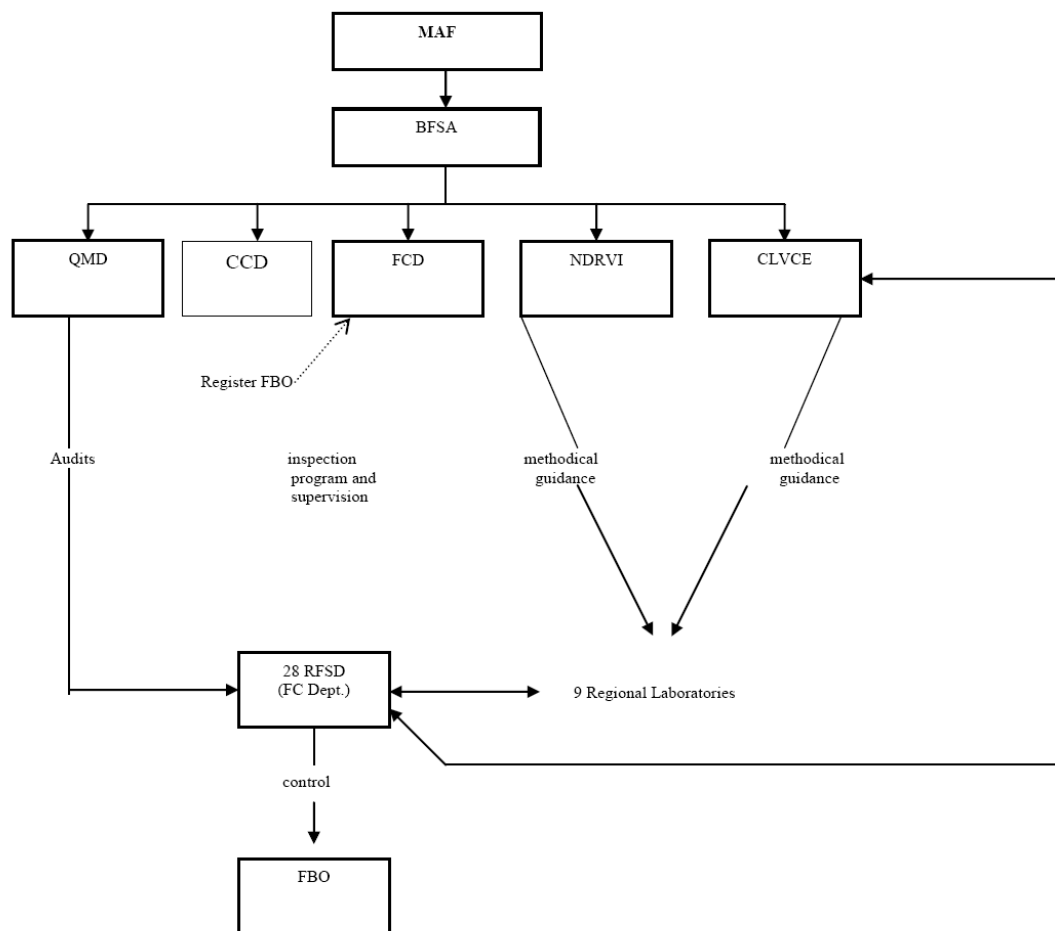
The NRCAH incorporates the following NRLs: NRL Rabies and monitoring the effectiveness of rabies vaccination; NRL for Brucellosis in animals; NRL for TSEs; NRL Parasites (in particular Trichinella, Echinococcus and Anisakis); NRL for Leptospirosis in animals; NRL "Tuberculosis and Anthrax", NRL for Enzootic bovine leucosis;

The Testing Laboratories' are: NRL "Fish diseases, mollusc diseases and crustacean diseases" and 'Testing Laboratory for exotic and extremely dangerous infections' that includes NRL „Foot-and-mouth disease and swine vesicular disease; NRL "Classical and African swine fever", NRL "Avian influenza and Newcastle disease" and NRL for African horse sickness.

Pursuant to establishment of BFSA, NDRVI encompassed further two (2) regional 'Testing Laboratories' (in the towns of Stara Zagora and in Veliko Tarnovo) , which have been restructured and renamed as such on the basis of the previously existing regional veterinary institutes in the same towns. Both testing laboratories have their accreditation for serological diagnostics of CSF. Currently these are updating their 2010 application to the BAS to be further accredited (as an enhanced scope of accreditation which is in process of accreditation for TSE, brucellosis, leucosis, and leptospirosis in animals).

Within the Regional Food Safety Directorates in Shumen, Blagoevgrad, Vratsa, Sliven, Haskovo, Plovdiv and Varna there are laboratories, which perform diagnostic serological testing in the animal health area. The 7 regional testing laboratories within the RFSDs, are accredited according to IEC EN ISO 17025 and are methodologically guided by the relevant NRLs within the NDRVI.

2.2 Control system for food of animal origin



| | |
|----------|---|
| MAF | Ministry of Agriculture and Food |
| BFSA | Bulgarian Food Safety Agency |
| QMD | Quality management Directorate |
| FCD | Food Control Directorate |
| NDRVI | National Diagnostic and Research Veterinary Institute |
| CLVCE | Central Laboratory for Veterinary Control and Ecology |
| RFSD | Regional Food Safety Directorate |
| FC Dept. | Food control Department |
| FBO | Food Business Operators |

Competent authorities

The Central Competent Authority for controls of food of animal origin is the BFSA. The Food Control Directorate (FCD) has 26 staff and is responsible for legislation and policy making in the area of veterinary public health control. It manages, organises and coordinates the activities of the RFSD in regard to preventive, regular and permanent veterinary inspections on animals in slaughterhouses, raw materials and products of animal origin in establishments producing or processing food of animal origin. Official control includes supervision of general activity establishments and retail establishments trading solely in products of animal origin too.

Approval and register of establishments

A procedure for approval and registration of Food Business Operators (FBO) has been established.

The establishments are evaluated by a two-step evaluation procedure. The first step is submission of an application form with self assessment of the food business operator to the relevant RFSD. With an order issued by the Director of the relevant RFSD the

commission is appointed, which, carries out an audit in the establishment for compliance with EU requirements and National legislation and draws the final conclusions. The president of the commission is designated by the Executive Director of the BFSA.

The register of all FBOs in Bulgaria is kept centrally by the BFSA. The Software for the national register of establishments is under development. The lists of approved establishments for both intra-EU trade and national market are published on:

<http://www.babh.government.bg/en/registers.html>

Official controls and inspection at establishments

The FCD prepares an annual inspection programme and supervises its implementation which is carried out by the RFSD. It also prepares manuals, instructions and checklists for the purpose of inspections and audits in the establishments. Each RFSD develops a detailed annual programme for official controls of each FBO in the region. The frequency of visits is determined by evaluation of risk assessment which is made in accordance with "Instructions on the Application of MANCP of Raw Materials, Foods, Food Ingredients, Food Additives and Materials in Contact with Food 2011".

A Better efficiency of the system for official controls is provided through the abovementioned instruction, thereby ensuring safety in production, storage and supply of raw materials and foods, food additives and food contact materials. The directors of the RFSDs define teams of three inspectors who by visiting the establishments for production, processing, storage and wholesale of raw materials and food of animal origin, carry out risk assessment. Inspection teams must complete a form for risk assessment. The head of "Food control" department upon checks on site, verify the categorization of the establishments, made by the inspection team.

The assessment of the risk level is based on determining the impact of the 12 basic criteria directly affecting the probability of occurrence of the major hazards. These criteria are: buildings and technological equipment; capacity of the establishments; assortment technology (type of products); origin and quality of raw materials and foods; water sources; self-control systems; qualification and training of establishment's personnel; laboratory monitoring; management of the establishment; RASFF and records of the establishment (as regards results of inspections, checks and audits performed for the official control).

The criteria for risk assessment of FBOs dealing with storage and trade of foods are as follows: buildings and technological equipment; capacity of the establishments; assortment; origin and quality of raw materials and foods; water sources; self-control systems; qualification and training of establishment's personnel; RASFF and records of the establishment (as regards results of inspections, checks and audits performed for the official control).

To determine the frequency of the control in the establishments for production, trade with foods of non-animal origin and catering facilities the following criteria are used: compliance of buildings and equipment with the activity performed; establishments' capacity; the type (assortment) of the manufactured or offered foods, the effectiveness of the self-control system; location of the establishment (markets, public transport stops, crossings, etc.) and the number of clients (human flow).

The frequency of inspections of the sites for production, processing, storage and wholesale of raw materials and foods of animal origin, of the sites for production, processing, storage and wholesale of raw materials and food of non-animal origin, food

contact materials, food additives food supplements, retail and catering must comply with the instructions.

The establishments producing, storing and marketing of foods are grouped in accordance with the sum of the points (based on risk assessment of possible risks) in one of the following categories, depending on which is determined the frequency of official controls on site:

Group I - high-risk establishments - visit at least 1 time per week applicable to sites for production, yielding and storage of foods of animal origin and **at least once a month for establishments** for yielding, production, storage and marketing of foods of non-animal origin.

Group II - medium risk establishments - visit at least 1 time per 2 weeks for sites for yielding, production, storage of foods of animal origin and **at least every three months for establishments** for yielding, production, storage and marketing of foods of non-animal origin.

Group III - low risk establishments - visit at least 1 time per month for sites for yielding, production and storage of foods of animal origin and **at least every six months for establishments** for yielding, production, storage and marketing of foods of non-animal origin.

Besides checks based on risk assessment in the instruction; there are thematic inspections of sites:

1. Regulations (EC) No 178/2002, 852/2004, 853/2004, 854/2004, 882/2004, 2073/2005, 2074/2005, 2075/2005, 2076/2005 and their amendments;
2. Of milk processing establishments of category II and III in accordance with the Treaty of Accession of Bulgaria to the EU;
3. Animal welfare during slaughter and during transport in accordance with Directive 93/119/EC and Regulation (EC) No 1/2005;
4. Control measures with regard to CSF in accordance with Decision 2008/855/EC and Directive 2002/99/EC;
5. Control measures on TSE and Scrapie in accordance with Regulation (EC) No 999/2001;
6. Collection, storage and submitting for disposal of ABP in accordance with Regulation (EC) No 1069/2009;
7. Ordinance on the requirements on labelling and presentation of foods;
8. With regard to the presence of GMO and labelling of finished products, containing GMO;
9. Regulation (EC) No 1333/2008 of the European Parliament and the Council of 16 December 2008 on food additives and Ordinance No 8/2002 on the requirements for use of food additives;
10. Ordinance No 3 of 04.06.2007 on the specific requirements applicable to materials and objects, other than plastics, intended for contact with food;
11. Ordinance No 2 of 23.01.2008 on the materials and objects of plastics, intended for contact with food;
12. Ordinance No 119 of 21.12.2006 on the measures for control on certain substances and residues thereof in live animals, raw materials and foods of animal origin, intended for human consumption;
13. Ordinance No 31 of 29.12.2003 on the maximum residue limits of pesticides in foods;

14. Ordinance No 31 of 08.10.2004 on the maximum residue limits of contaminants in foods;
15. Commission Regulation (EO) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs;
16. Commission Regulation (EC) No 669/2009 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC.

Committees appointed by an order of the Directors of the RFSD conduct evaluations of the HACCP system implemented in establishments on the territory of the relevant region. The frequency of these evaluations is at least once a year to establishments producing food of animal origin and once every two years to establishments producing food of non animal origin. Officials with professional experience and who have completed training on HACCP are part of the teams. The inspector, which is responsible for the control on the establishment, is also present during the assessment, but he is not a member of the assessment committee.

The Directors of the RFSDs organize the performance of official control under the following principle: The official veterinarians who perform continuous monitoring of slaughterhouses, poultry slaughterhouse, wild game establishments and customs warehouses, are determined by an order. For the other establishments it is not necessary to determine the official by an order. Establishments, controlled indicators and inspectors who will carry out the checks, are determined if possible at least once every six months, according to the developed annual plan of inspections and audits, by the head of "Food control" Departments, agreed with the director of the relevant RFSD.

Upon order, issued by the Executive Director of the BFSA, other thematic checks are carried out as well, which are outside the scope of the Instruction.

In case of signals and complaints, submitted by consumers, immediate checks are carried out, in addition to those, foreseen in the Instruction.

The RFSD reports the results of the controls to the FCD on a monthly basis.

The FCD has developed instructions on the implementation of the MANCP when it is needed. Based on the instructions and the criteria for risk assessment, each RFSD draws up a plan for official controls for each establishment. The plan includes the frequency of control exercised by the official veterinarians and heads of FCD. A review of the instruction has been carried out in May 2011 based on the experience acquired with the implementation of the MANCP.

The total number of RFSD inspectors carrying out the veterinary public health controls is 617, of whom 495 are official veterinarians.

The "Quality Management" Directorate performs audits of the RFSD. These also include audits in the area of veterinary public health control.

Establishments in transition

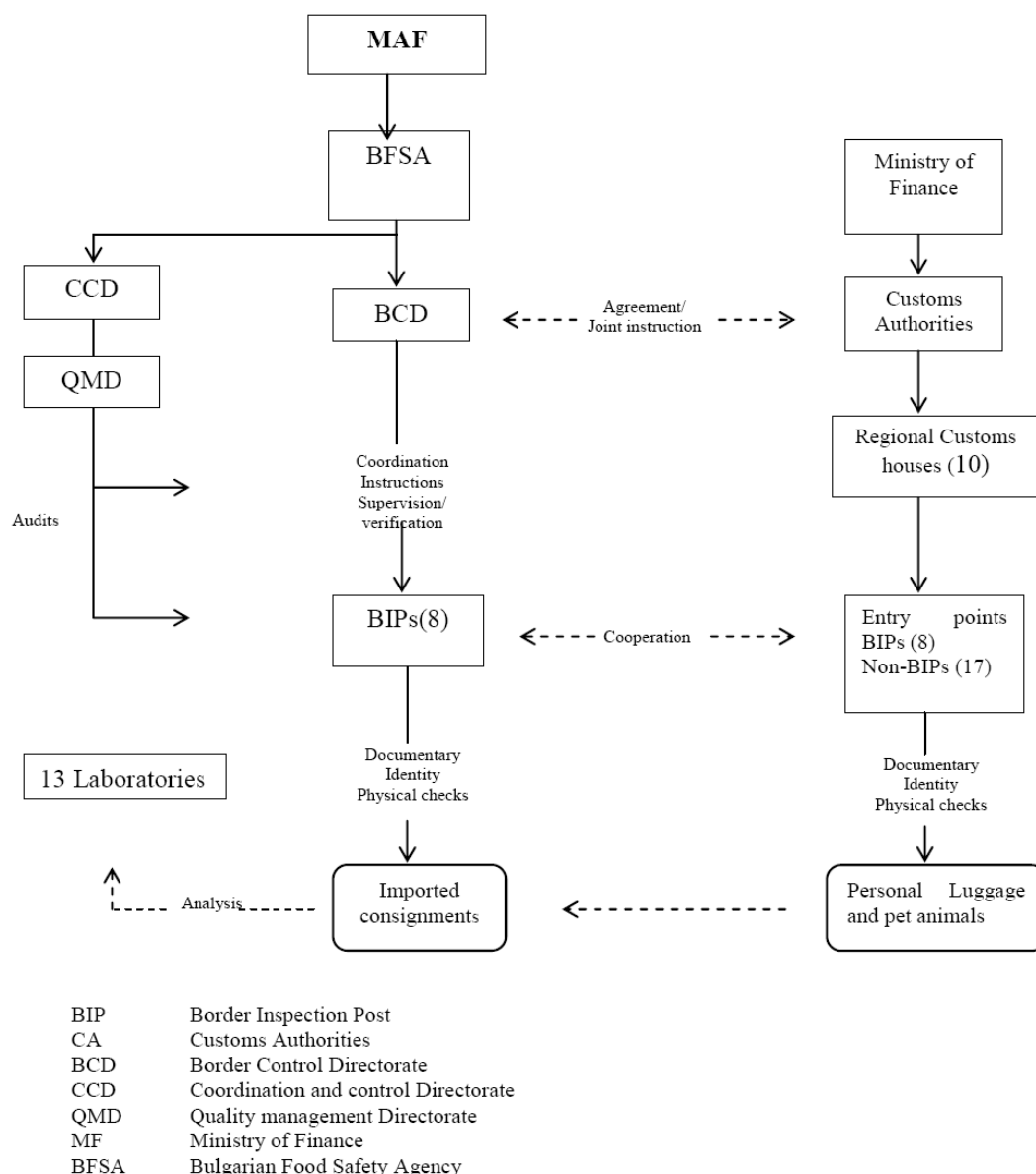
Commission Decision 2009/861/EC lays down a transitional period to the end of 2013 for milk processing establishments which process non-compliant milk with the requirements laid down in Annex III, Section IX, Chapter I, point III of Regulation (EC) 853/2004.

Laboratories

Routine laboratory testing of products of animal origin are performed by 9 regional testing laboratories within the RFSDs, the confirmation of positive results is performed by the NDRVI. The 9 regional testing laboratories within the RFSDs, are accredited according to IEC EN ISO 17025. The results of analyses are sent to the RFSD and in the case of serious findings, are also communicated to the FCD.

Laboratory analyses for residues, pollutants and contaminants are carried out by the CLVCE. Within the scope of accreditation of the CLVCE raw materials and products of animal origin, biological fluids and honey are also included. By order No PД 09-773 / 15 September 2011, issued by the Minister of Agriculture and Food, 5 NRLs within the CLVCE are defined.

2.3 Control system for imports of food of animal origin



Competent authorities

The CCA (Central Competent Authority) for import controls of products of animal origin and live animals is the BFSA. The Border Control Directorate (BCD) is responsible for policy making and co-ordination of controls. The directorate drafts legislation, issues instructions and monitors the activities of the BIPs. Twenty five border posts (8 BIPs and 17 non-BIP entry points) have been designated in Bulgaria.

The National Customs Agency under the Ministry of Finance is organised in 10 Regional Customs Houses and another 64 inland and border customs offices on a local level.

Import controls

The monitoring programmes, instructions and checklists for import controls developed by the BCD are disseminated and available in all BIPs. The BIPs submit monthly reports to the BCD on controls carried out. The TRACES registration system is used to record data on consignments. Planned supervisory checks on a verification of proper implementation of EU legislation by BIPs official veterinarians are carried out by BCD at central level for each BIP twice per year.

Audits of the operation of BIPs are foreseen to be performed. Customs Authorities support veterinary authorities for identification and selection of incoming consignments for veterinary checks. The CA together with the BFSA also carries out import controls on personal luggage.

All necessary checks (documentary, identity and physical) are carried out at 8 BIPs listed in the table below. The individual BIPs are under the direct authority of the RFSD. BIPs staff check import controls on live animals and animal products, imports of animal feedingstuffs and veterinary medicinal products.

| BIP | Border | Type | Approval |
|------------------|---------------|-------------|------------------|
| Bregovo | Serbia | Road | HC, NHC |
| Burgas | Black Sea | Port | HC, NHC |
| Gueshevo | FYROM | Road | HC, NHC |
| Kalotina | Serbia | Road | HC, NHC, U, E, O |
| Kapitan Andreevo | Turkey | Road | HC, NHC, U, E, O |
| Sofia | n.a. | Airport | HC, NHC, E, O |
| Varna | Black Sea | Port | HC, NHC |
| Zlatarevo | FYROM | Road | HC, NHC |

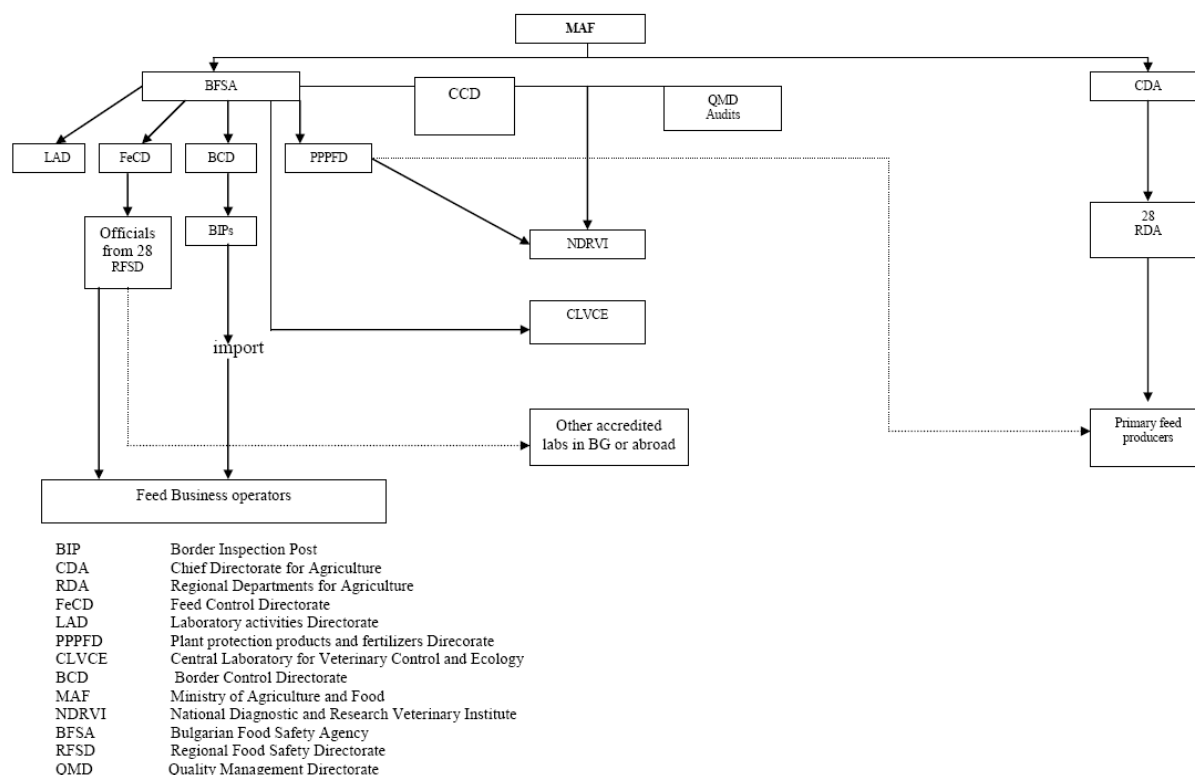
Co-operation between Customs and the BFSA takes place under a high level agreement. Implementation takes place through a joint instruction between Customs and BFSA. At local level, co-operation takes place through exchange of information in relation to the positive list and regular meetings at entry points between official veterinarians and Customs officials.

Customs Authorities support veterinary authorities for identification and selection of incoming consignments for veterinary checks. Customs officers together with the officials from BFSA also carry out import controls on personal luggage.

Laboratories

Laboratory tests of imported products of animal origin are performed in the laboratories of the RFSD, CLVCE and NDRVI.

2.4 Control system for feedingstuff and animal nutrition



Competent authorities

The CCA for feedingstuffs and animal nutrition is the BFSA. Within the structure of BFSFA, within the headquarters, there is a newly established directorate which is responsible for official controls on animal nutrition, namely the FeCD. It has 11 employees and organises execution of control activities under the Feed Law and the Veterinary Act.

Taking into account that controls on feedingstuffs are associated with other control systems, appropriate links and procedures for interaction between directorates (CCD, PPPF Directorate, FCD, AHWD, LAD) have been set up in order to provide co-ordination, exchange of information and proper interaction.

A Contingency plan, updated in accordance with the structure and activities of the BFSFA, has also been worked out. It is published on the web-site of the agency.

Approval and register of establishments

The BFSFA is the CA responsible for the approval and registration of feed business operators. In the RFSD, 56 staff are in charge to approve and register feed business operators as well as to execute official control on feed sector on the whole.

Registration and approval of feed business operators is done on the basis of Regulation (EC) No 1831/2003 and procedures to be performed are available in the Feed Law (SG No. 55/2006, last amended SG 8/2011).

Applications for approval are submitted to the director of the respective Regional Directorate where the manufacturing or trade site is situated. A subsequent check on the spot is carried out in order to find out whether the applicable requirements have been met. A report with findings and recommendations is made. Within six months, the establishment must comply with the relevant requirements in order to be approved.

Registration of operators is done by the same structural units following the respective procedures.

Primary producers of feedingstuffs are registered under Regulation (EC) No 183/2005 by the 28 District Agriculture Directorates of the Chief Directorate Agriculture (CDA), which is a unit within the structure of the MAF.

Following the requirements of Regulation (EC) No 183/2005, the FeCD maintains national public registers of approved establishments and of representatives of enterprises dealing with importation of feed from third countries. The national registers are a collection of the regional ones, which are maintained by the Regional Directorates of the agency.

The said registers are available on website: www.babh.government.bg

Directives 98/68/EC and 98/51/EC have been transposed into the national legislation by Ordinance No. 109 on the official control of feedingstuffs (SG 84/2006, as last amended in SG 20/2012). The regional structures of BFSAs keep details of approved and registered representatives for feed imports from third countries – www.babh.government.bg

Official controls

Official control is carried out under the requirements of Regulation (EC) No 882/2004. It is carried out at all stages of production, processing, storage, transportation, distribution and use of feedingstuffs. Control activities start from the primary production of feeds and finishes with the use of feedingstuffs by animals.

Official control is based on risk assessment. The following data is considered: risk in relation to feed; activities connected with production taking account of: processing, storage, transportation, distribution and animal feeding; available data from official control; reliability of own-checks of feed business operators and recommendations from the Commission. For the categorisation of risk for performance of checks of feed establishments, the criteria for detection of probability and the severity of each event are used.

Samples are taken based on the risk and in cases of doubt and are analysed for compliance with the legal requirements and for observation of EU levels. Sampling is in accordance with Regulation (EC) No 152/2009. The sampling methods and analysis are in line with the requirements of Article 11 of Regulation (EC) No 882/2004.

When non-compliances are found, one or more of the following measures are taken: prohibition of marketing of feed and prescription; withdrawal the product from the market; use for other purposes or destruction. In case of system violations or non-application measures imposed by the CA, the registration of the operator is suspended and the operator is de-listed from the register.

The total number of staff, both at central and regional level, entrusted with the control of feedingstuffs is 67.

Organisation of the official control on feeds:

At regional level physical checks, inspections and audits of feed business operators are carried out. A number of 56 officials are performing the official control on feeds throughout the country. They are appointed as inspectors and experts, and by one in each of the 28 regional directorates, located to the administrative division of the country and whose duties are entirely related to official controls of feed. In each RFSD there is also an official veterinarian, appointed for the replacement in case of absence of the abovementioned official, who also issues health certificates for export of feed to third countries. These official veterinarians combine other duties as well in the RFSD.

All inspectors, experts and official veterinarians performing the official control have undergone training on feed legislation and all 56 officials mentioned are appointed as a regional contact points for the RASFF with regard to feed.

The obligations of each expert or inspector, responsible for official control on feed are:

- to prepare an annual plan on the bases of risk assessment, to allocate it in monthly and weekly periods, in accordance with the guidance, provided at central level;
- to report weekly the official control performed by him, through sending copies of the documents, issued as a result of the official control;
- to comply with the provisions of the legislation and with the confidentiality of the information, when perform official control, and to work with the approved models of documents, check-lists and procedures;
- to participate in the trainings, organised at central level;

At central level there are 7 experts available of the foreseen to be appointed at central level, in accordance with the Statutes of the BFSA. The directorate is functioning as a competent contact point for the RASFF, with regard to feed. The following activities are responsibility of the FeCD in accordance with the Law and Statutes of the BFSA:

1. Actively participate in the preparation of legislation, preparation of the template documents, drawing up check lists, operational procedures, procedures for co-operation and exchange of information between the RFSDs, between the RFSDS and the headquarters of the BFSA and between the directorates at central level and regional directorates;
2. Preparation of multi annual plan for control of feeds as an integral part of the multi annual plan of BFSA;
3. Annual submission for approval of a guidance for preparation and implementation of a framework plan for feed control, drawn up on risk assessment basis at regional level
4. Annually draw up an annual framework plan for control of feed, which is the sum of the plans drawn up based on risk assessment at regional level; if necessary, based on new information related to risk assessment as well as on the results of control gathered at national level, corrections are made in connection with the obligation to manage risk;
5. Monthly preparation of a report to the Executive Director of the BFSA concerning the implementations of the plans at regional level;
6. Implementation of orders, issued by the Executive Director of the BFSA with regard to verification of the control, carried out at regional level;
7. Proposals of training of the officials of the directorate and of the RFSDs.

The Border Control Directorate within the BFSA is responsible for border control of feedingstuffs through its 8 approved BIPs.

The Directorate for Control of Plant Protection Products and Fertilisers is responsible for the implementation of the monitoring on mycotoxins and pesticides in the plant production, intended for feed, and produced as primary production of agricultural crops for feed in accordance with the Feed Act (last amended by SG 8/2011).

Controls on imports

The competent authority for border control at BIPs is the BFSA. Importers are obliged to notify the BFSA of the place and time of import of each batch of feed 24 hours in advance. Inspectors of the BCD check whether the business establishment is on the list of the registered or approved representatives as required by Regulation (EC) No 183/2005. Prior to the release on the market of the imported products, inspectors carry out physical checks under the operational instructions and issue the standard document under Directive 98/68/EC. When the consignment is released for free circulation, feedingstuffs are controlled by the RFSDs.

Laboratories

Analyses of the samples taken by inspectors for feed controls are analysed in: laboratories of BFSA and other accredited laboratories in Bulgaria; and in some cases, in laboratories in other Member States.

Contracts were signed (No 41 /27.09.2011 between BFSA and Fytolab Ltd., located in Plovdiv and No 42 /27.09.2011 between BFSA and “SGS Bulgaria” OOD) for analyses of feeds on certain indicators as well as for confirmatory tests, when there is lack of capacity within BFSA.

| Indicators | Number of planned analyses 2011 | Number of performed analyses 24.04-31.12. 2011 | Number of planned analyses 2012 |
|--------------------------------------|--|---|--|
| Pesticides | - | 23 (one of which is for confirmatory analysis) | 57 |
| Mycotoxins for confirmatory analysis | 49 | 2 | 45 |
| Dioxins | 16 | 2 | 6 |
| GMO | 20 | 6 | 30 |
| Cobalt | 13 | 2 | 5 |

A working group has been appointed to contact accredited laboratories, situated in other Member States with the purpose to organise contracts for testing of certain indicators in feed. Contracts had been signed with two laboratories in Belgium and in Germany.

| Indicators | Number of planned analyses 2011 | Number of performed analyses 24.04-31.12. 2011 | Number of planned analyses 2012 |
|---|--|---|--|
| Screening of forbidden medicinal substances as feed additives or for cross-contamination of coccidiostats in non-target feedingstuffs | 183 | - | 139 |
| Quantification of coccidiostats | 48 | - | 42 |
| Quantification of colourants | 2 | - | 5 |
| Vitamin D ₃ | 20 | - | 12 |
| Antioxydants | 2 | - | 4 |

The contracts were signed (55/06.12.2011 between BFSA and LUFA-ITL and agreement with FLVVT Tervuren) for the analyses, as follow :Lasalocid sodium, Maduramycine ammonium alfa,

Monensin sodium, Robenidine hydrochloride, Salinomycine sodium, Narasin, Nicarbazine, Diclazuril, Semduramycine sodium, Vitamine D, Antioxidants, Colorants, Prohibited veterinarian drugs screening, as feed additives and inevitable contamination of non-target feed with coccidiostats (Avilamycin, Avoparcin, Erythromycin, Flavophospholipol, Ionophoric antibiotics, Lincomycin, Beta-lactam antibiotics, Spiramycine, Tetracycline, Tiamuline, Tylosin, Virginiamycine, Zink- Bacitracine).

Analyses of the samples taken by inspectors of the RFSD are carried out in the NDRVI Laboratory for Qualification of Grain, Grain Products and Fodders (LQGGPF) within RFSD in Sofia and CLVCE. Laboratory for Qualification of Grain, Grain Products and Fodders (LQGGPF) within RFSD in Sofia.

| Indicators | Number of planned analyses 2011 | Number of performed analyses 24.04-31.12.2011 | Number of planned analyses 2012 |
|------------------------------------|--|--|--|
| Fiber | 58 | 60 | 121 |
| Crude protein | 59 | 58 | 107 |
| Crude fat | 43 | 46 | 83 |
| Calcium | 34 | 31 | 56 |
| Phosphorus | 23 | 19 | 38 |
| Ash insoluble in hydrochloric acid | 11 | 5 | 12 |
| Urease activity | 12 | 4 | 12 |
| Crude ash | 17 | 20 | 37 |
| Magnesium | 2 | 5 | 14 |
| Copper | 100 | 71 | 123 |
| Zink | 74 | 45 | 78 |
| Iron | 39 | 20 | 32 |
| Manganese | 19 | 18 | 36 |
| Vitamin A | 56 | 37 | 55 |

NDRVI

| Indicators | Number of planned analyses 2011 | Number of performed analyses 24.04-31.12.2011 | Number of planned analyses 2012 |
|-------------------|--|--|--|
| Mycotoxins | 618 | 609 | 822 |
| Pesticides | 93 | 30 | - |
| Salmonella spp. | 104 | 82 | 148 |

| Indicators | Number of planned analyses 2011 | Number of performed analyses 24.04-31.12.2011 | Number of planned analyses 2012 |
|--|--|--|--|
| Salmonella in processed animal proteins (Control system "TSE") | 232 | 131 | 193 |

| | | | |
|--|------------|------------|------------|
| Sum Total of the number of samples taken for Salmonella spp. no matter the control system | 336 | 213 | 341 |
|--|------------|------------|------------|

CLVCE

| Indicators | Number of planned analyses 2011 | Number of performed analyses 24.04-31.12.2011 | Number of planned analyses 2012 |
|-------------------|--|--|--|
| Arsenic | 66 | 54 | 81 |
| Cadmium | 87 | 70 | 107 |
| Lead | 93 | 74 | 117 |
| Mercury | 54 | 44 | 66 |
| Selenium | 24 | 5 | 21 |

CLVCE

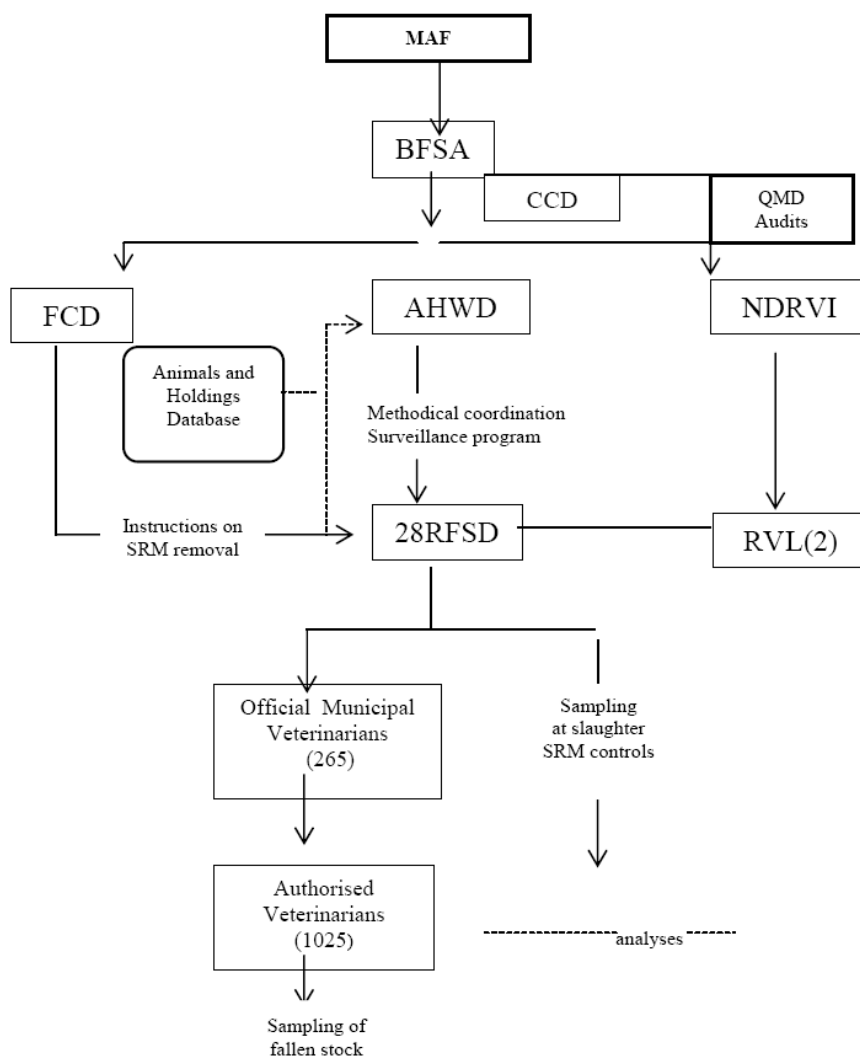
Sample from feedingstuff manufacturers (except primary agricultural production) in 2012: Arsenium - 24, Cadmium - 40, Lead - 47, Mercury - 21 analyses (132 number of analyses, 47 number of samples); Additive manufacturers and traders 2012: Cadmium - 1, Lead - 1; Premix manufacturers and traders 2012: Cadmium - 7, Lead - 7 (14 number of analyses, 7 number of samples); Compound feed manufacturers 2012: Arsenium - 24, Cadmium - 26, Lead - 28, Mercury - 16 analyses (94 number of analyses, 28 number of samples); Farms 2012: Arsenium - 33, Cadmium - 33, Lead - 34, Mercury - 29 analyses (129 number of analyses, 34 number of samples); Received samples in CLVCE for January-December 2011 (number of analyses - 290, number of samples - 85): Arsenium - 62, Cadmium - 72, Lead - 75, Mercury - 48, Selenium - 5, Cupper - 1, Chlororganic compounds - 2, Humidity - 25.

Received samples from BIPs in CLVCE for 2011 (number of analyses - 130, number of samples - 31): Arsenium - 32, Cadmium - 29, Lead - 29, Mercury - 4, Humidity - 28, Radionucleids - 8.

The confirmation of positive results is carried out in other accredited laboratories in Bulgaria under contracts - Fytolab and SGS, and abroad - LUFA-ITL and FLVVT Tervuren.

2.5 Control system for TSE and Animal By-Products (ABP)

TSE (Transmissible Spongiform Encephalopathy)



| | |
|--------------|---|
| BFSA | Bulgarian Food Safety Agency |
| RFSD | Regional Food Safety Directorate |
| AHWD | Animal Health and Welfare Directorate |
| FCD | Food Control Directorate |
| NDRVI | National Diagnostic and Research Veterinary Institute |
| RVL | Regional Veterinary Laboratories |

Competent authorities

The central competent authority for TSEs controls is the BFSA.

The AHWD is responsible for policy and transposition of legislation on TSEs. It develops the epidemio-surveillance monitoring programme and instructions on the removal and control of SRM. It also issues general instructions and operational procedures regarding BSE clinical suspects and is also responsible for the development of contingency plans.

Monitoring and surveillance of TSE

Samples for TSEs must be taken by official veterinarians at slaughterhouses or by APV on farms in the case of fallen stock or emergency slaughter.

Within the active surveillance programme, testing of bovines must cover: all animals over 24 months that died on farms or during transport; all emergency slaughtered animals over 24 months; all animals over 30 months intended for human consumption and all animals over 24 months found sick at ante-mortem inspection. Within the passive surveillance programme, all bovine animals showing clinical signs similar to those of TSEs, irrespective of their age, are tested by pathology, immunohisto-chemistry or immuno-blotting.

Within the TSE surveillance programme for small ruminants, random samples of sheep and goats over 18 months intended for regular slaughter and human consumption must be tested. Samples of all dead sheep and goats over 18 months must be also tested as well as all sheep and goats that have shown clinical signs characteristic to TSE irrespective of their age.

Specified Risk Material (SRM)

Measures to control SRM have been introduced by the FCD. Official veterinarians responsible for official controls of removal and staining of SRM in slaughterhouses and cutting plants, are also responsible for guaranteeing their proper disposal. In addition, the RFSD carry out regular supervisory inspections in establishments.

The SRM and dead animals must be collected from the whole territory of the Republic of Bulgaria and rendered harmless in one of the two rendering plants – in Shumen and Varna, in accordance with Order RD 09-137/28.02.2006, issued by the MAF. With this order the territory of Bulgaria is separated into two regions in terms of collection of ABP, and the rendering plant which serves the relevant region is defined. The establishments and plants which generate SRM must have a contract with the relevant rendering plant. The mayors of the settlements and the official veterinarians are responsible to inform the rendering plant in case of dead animals in order to organize their collection. The rendering plants have schedule and routes for the collection of dead animals and other ABPs.

The SRM) and dead animals must be collected from the whole territory of the Republic of Bulgaria and rendered harmless. For this activity the BFSA signed contracts with the two rendering plants.

Total Feed Ban

The total feed ban entered into force in January 2006. At present control on the total feed ban is carried out by regional directorates, under supervision by the FeCD. Observance of the total feed ban by feed business operators is monitored through annual inspection plans, consistent with the multi annual control plan. Guidelines concerning elaboration and implementation of the annual control plan, risk assessment and risk analysis at national level, as well as risk management, are drawn up at central level then disseminated to the regional directorates. The said guidelines are based on risk assessment done on the ground of the results gained during the previous periods under review and current situation of the legislation and feed sector. The worked out draft plans at regional level are sent to the headquarters, reviewed if necessary, consolidated and approved by the Executive director of the BFSA and sent back to the regional services for implementation as it is required by the law.

Laboratory testing is carried out by the approved laboratory within the structure of NDVRI – Sofia. The costs of the laboratory tests for feed ban control are covered by the State. There have been no cases of positive results in the samples taken to date.

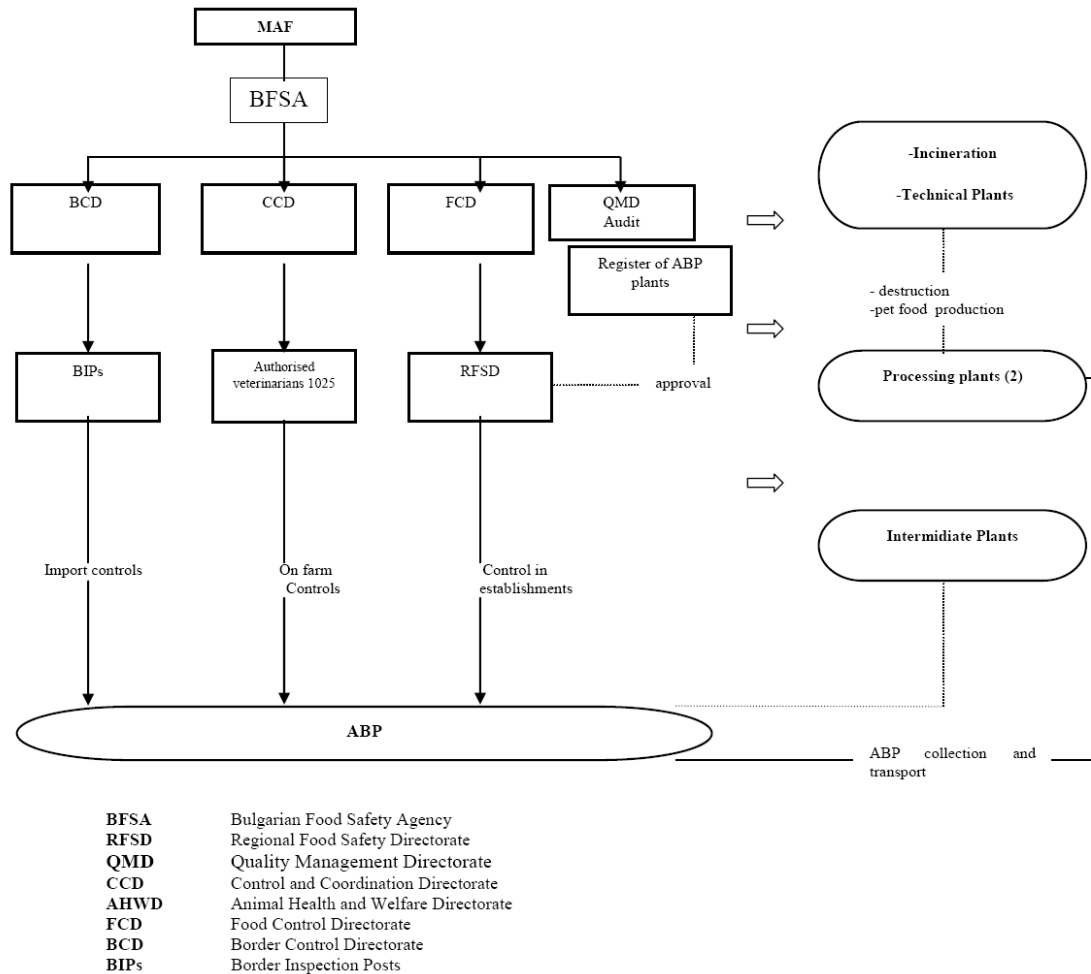
So far, due to the fact that there are no arrangements in the Veterinary Law for approving operators who use animal proteins in the production of feedingstuffs (under Annex IV to Regulation (EC) No 999/2001), such approval have not been applied. It is expected that such texts will be available and the process of approval will start after the adoption by the National Assembly of the draft amendment and supplement of the Law on veterinary activity.

Laboratory services

The diagnostic testing on TSE is carried out by approved rapid tests in the NRL of the NDRVI in Sofia. Confirmation tests are carried out in the NDRVI by patho-histology and immuno-blotting.

The rapid tests used are Platelia “Biorad” tests, based on the sandwich ELISA principle with use of monoclonal antibodies for detection of abnormal prion proteins and Ceditest based on the chemiluminescent ELISA method. Confirmatory analyses are tested patho-histologically or by immunohisto-chemistry or immuno-blotting.

ABP (Animal By-Products)



Competent authorities and official controls:

The BFSA is the central competent authority responsible for supervision and controls throughout the ABP chain. The FCD is dealing with public health issues in processing establishments for food of animal origin and official control at retail level, official control in case of export of ABP-products, official control of approved establishments for Intra Community trade with food products of animal origin, covered by Regulation (EC) No 1069/2009 (Intermediate plants, Storage plants, Processing plants, Oleo-chemical plants, Pet food plants, Technical plants, Incineration / Co-incineration plants).

The AHWD within the BFSA is responsible for fallen stock and collection, transport and processing, and the BCD - for imports, exports and transit.

Organisation of veterinary sanitary controls at sites producing, processing and storing foods of animal origin. Furthermore at the respective approved plants performing activities subject to the rules laid down in Regulation (EC) 1069/2009 and respectively Regulation (EC) 1774/2002 before 4 March 2011.

On the basis of the Instruction for implementation of the MANCP for controls of ABP, there is an Annual Plan developed to ensure performance of following tasks or activities:

- Directly supervision of establishments/ plants subject to controls;
- Assessment of HACCP systems carried out by special commission of the relevant RFSD;

- Annual programme of internal audits by Food Control Departments chiefs in the plants for production, processing and storage of food of animal origin. One of the subjects is auditing the compliance with all the requirements of Regulation (EC) 1774/2002, respectively Regulation (EC) 1069/2009. The frequency of inspections /checks/ and audits planned is determined on the basis of risk analysis in accordance with the criteria, formulations, digital values and forms for risk analysis, which are laid down in the Instruction.

Inspections and audits are documented in protocols and reports that include the subject of the inspection or audit and all non-compliances identified. Based on the found deficiencies, the official veterinarian issues prescriptions /orders/ with a deadline for correction. Such document is been delivered to the business operator concerned, who is obliged to address those deficiencies within the deadline prescribed, as provided for in the Law on Veterinary Activity. If these Prescriptions are not fulfilled, and in case that the non-compliances are very serious and might result in potential risk for animal and/or public health, the official veterinarian might issue an Order for temporary suspension of a part or of the whole activity of the plant concerned or for withdrawal of its authorization, as provided for in the Law on Veterinary Activity. Depending on the non-compliances detected, the aforementioned measures might be accompanied by imposition of the punitive sanctions laid down in the Law on Veterinary Activity.

Category 1 processing plants (the two rendering plants in Shumen and Varna) are controlled by official veterinarians, which are present daily and perform checks on the production process. The co-incineration of produced Meat and Bone Meals (MBMs) in the cement plant, village of Beli Izvor, Vratsa region, is also under the control of official veterinarian.

Collection, processing and disposal of ABP

Annually a contract is signed by and between BFSA and the rendering plant in the town of Shumen, under which this rendering plant undertakes the obligation to offer services to 18 administrative districts (out of 28 in all). From the territory of these districts the rendering plant collects and renders harmless materials of categories 1, 2 and 3, whereas the materials of categories 1 and 2 and the materials of category 3 are processed separately in two individual technological lines. The MBM from processing of materials of categories 1 and 2 is forwarded for final incineration in the cement plant in the village of Beli Izvor. The by-product fats are used after that as an alternative fuel in the rendering plant itself. The quantities of MBMs from the processing of materials of category 3 left unused (a small part is used to prepare foods for home pets) is also to be forwarded for further incineration to the cement plant and the by-product fats are to be used for technical purposes.

Annually a contract is signed by and between BFSA and the rendering plant in the town of Varna, under which this rendering plant undertakes the obligation to offer services to the remaining 10 administrative districts. From the territory of these districts the rendering plant collects and renders harmless materials categories 1, 2 and 3, whereas the materials of all the three categories are processed in one and the same technological line. For that reason the enterprise is ranked as category 1 and is obliged therefore to deliver all the by-products (MBMs and fats) for destroying. The MBMs are to be forwarded for final incineration in the cement plant in the village of Beli Izvor.

The districts serviced by the rendering plants are specified not only in their respective contracts with the BFSA, but also in Order No. RD09-137 dated 28.02.2006 issued by the Minister of Agriculture and Forestry.

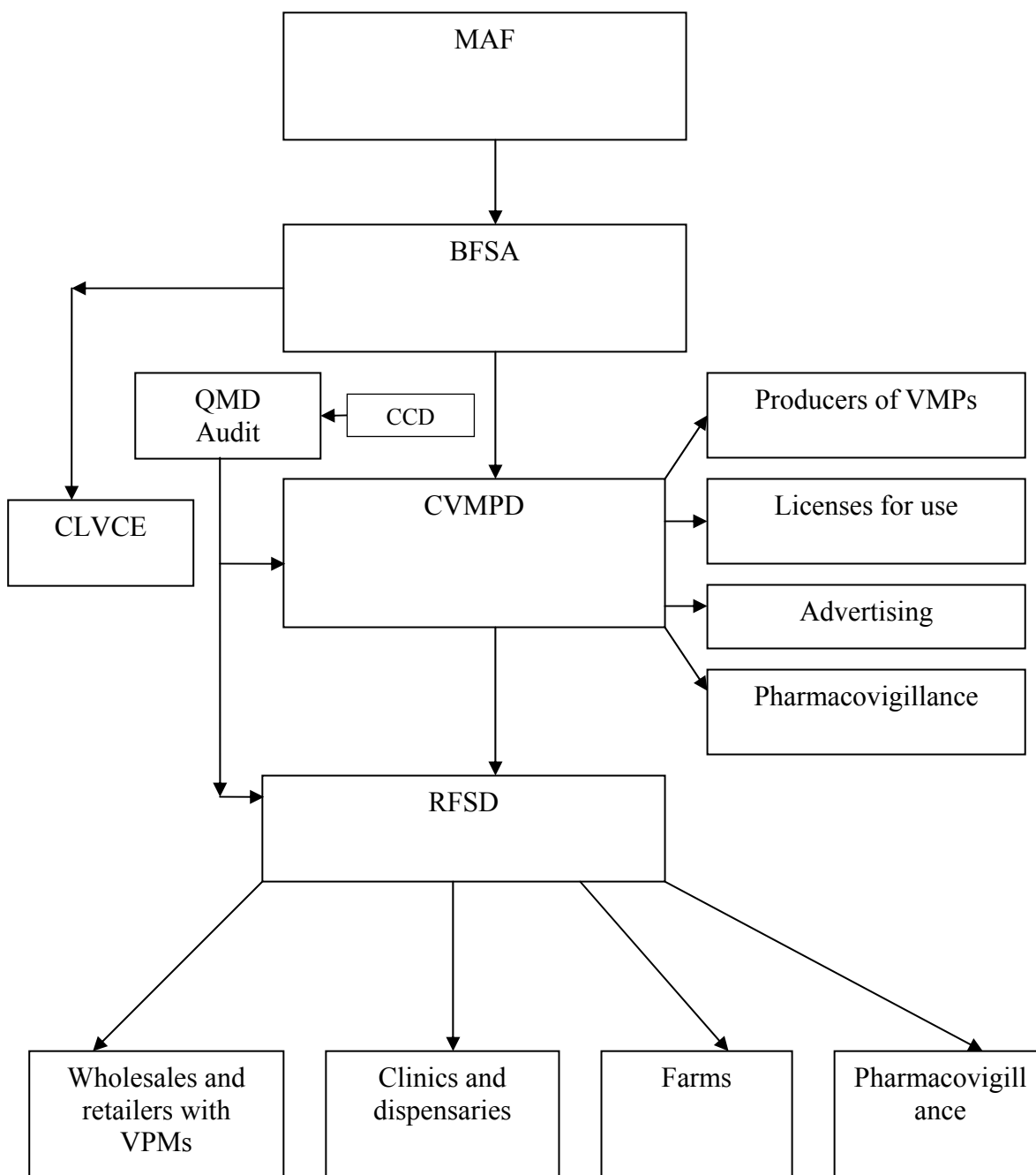
1. One plant is in charge for the collection of the dead animals from specific territories.
 - a) The rendering plant has prepared and submitted to BFSA a scheme of a transport system, which includes 8 transport routes, specifying:
 1. the places (towns and villages) each route passes through;
 2. a list of the sites, which are to be offered services (farms, meat production and meat processing facilities);
 3. the days of the week, on which the truck travel along these routes;
 4. the names of the drivers and the registration numbers of the trucks travelling along these routes, whereas two extra trucks are enlisted too;
 5. the mobile telephone numbers of the drivers;
 6. a route map showing the district covered by the respective transport route.
 - b) For the collection of SRMs, a scheme has been prepared and submitted to NVS describing the transport system, which includes 4 transport routes containing the same data as these specified in a).
2. The other plant offer services to services to 10 districts:
 - a) For the collection of the dead animals from these territories the rendering plant has prepared and submitted to BFSA a scheme of a transport system, which includes 8 transport routes containing the same data as these specified in the transport routes mentioned above.
 - b) For the collection of SRM, the same transport routes are used.

Financing from the state budget is provided, as follows:

1. 100% of the costs concerning the collection, transportation, processing and eradication of the dead animals;
2. costs concerning the grinding, packaging, transportation and eradication of the meat and bone flour being a by-product from the incineration of specific risk materials and materials category 3.

The meat production and meat processing facilities and the commercial sites pay to the rendering plants for the transportation and the processing of the by-products of animal origin they supply to them.

2.6 Control system for veterinary medicinal products (VMP) and residues



| | |
|--------------|--|
| CVMPD | Control on VMPs Directorate |
| MAF | Ministry of Agriculture and Food |
| BFSA | Bulgarian Food Safety Agency |
| QMD | Quality management Directorate |
| RFSD | Regional Food Safety Directorate |
| CLVCE | Central Laboratory of Veterinary Control and Ecology |

Competent authorities

The central competent authority for VMPs and their residues in live animals and animal products is the BFSA - Control on VMPs Directorate (CVMPD) and the CLVCE. The implementation of controls is assigned to official veterinary inspectors of the RFSD. One official veterinarian in each RFSD is responsible for VMPs and their residues.

VMP

Authorisation and control of the VMPs

The BFSA is responsible for the authorisation and control of VMPs. The CVMPD co-ordinates the implementation of wholesale, retail, storage, use and advertising of VMP by the RFSD.

Experts of CVMPD participate in the drafting of regulations, guidelines, procedures, instructions and samples of documents related to the official control of VMP, participate in working groups, standing committees and meetings at national and international institutions associated with its activities. They also evaluate dossiers and the quality of VMP, issue renewals and change of marketing authorizations on national procedures, mutual Recognition and Decentralised procedure and report the evaluation of the dossier and the quality of VMP:

- assess and give a statement on the evaluation report and documentation of the dossier country of reference procedures for Mutual Recognition and Decentralised procedures marketing authorisation of VMP;
- participate in the commissions according to art. 286, par. 1, Art. 347, par. 1 and Art. 365, par. LVA 1;
- prepare public reports assessing the VMP and annual report on controlled VMP that are sent to the European Directorate for the Quality of Medicines and Health;
- assess periodic safety reports of VMP;
- prepare a statement to the Executive Director on the received reports of adverse reactions in marketing, other information obtained in system pharmacovigilance and variations in the quality of VMP;
- check the documentation relating to applications for approval of advertisement VMP and issue a statement to the Executive Director;
- examine the applications and attached documentation for the issuance or change of authorizations: a) Manufacturing of VMP; b) Wholesale of VMP;
- retail sale of a veterinary medicinal product;
- prepare authorization for manufacturing, marketing, wholesale and retail VMP, Certificates of Good Manufacturing Practice and documents related to the control of the marketing; license for VMP containing narcotics substances
- control for compliance with Good manufacturing practice for manufacturing of the VMP and APIs;
- keep registers with all issued authorizations for: a) Manufacturing of VMPs; b) Wholesale of VMPs; c) retail sale of VMPs; and d) marketing of VMPs;
- submit information in the database EudraGMP for issued Manufacturing authorizations of the VMP and Certificates of Good Manufacturing Practice and introduce and exchange information in a communication network and tracking procedures Mutual Recognition and Decentralised procedures;
- co-ordinate and control the information provided in the pharmacovigilance system vigilance and provide it with the competent authorities of Member States and the EMA information about suspected serious adverse reactions observed in territory;
- make proposals to the Executive Director to revoke the authorization of manufacturing, wholesale, retail and marketing to ban use and marketing of a batch of VMP for blocking and withdrawal in cases provided for in LVA;

- prepare an annual inspection program for the official control of the VMPs and it submitted for approval by the Executive Director;
- involved in developing training programs for control of the marketing.

Official controls on marketing and use of VMPs

The CVMPD is responsible for control of marketing authorisation, manufacture; distribution and advertisement of VMPs. Inspectors of the RFSD and the CVMPD carry out the inspections. One official veterinarian is responsible for control of VMPs at each RFSD. An annual inspection programme is devised at central level. The minimum inspection frequency for wholesale, retail (pharmacies) and private practitioners is at least once per year. Checklists are prepared by the CVMPD and disseminated to all RFSD. Analyses of the samples are carried out by the National Diagnostic Veterinary Research Institute.

Instructions had been provided for the inspection of on-farm establishments for the control of the use of VMP and medicated feedingstuffs.

Concerning the control on prescribing, production, labelling, transportation and use of medicated feedingstuffs, it is executed by FECD through the regional directorates of the agency.

Residues

Official controls on residues

The National Residue Control Plan (NRCP) is prepared and drafted by LAD together with CVMPs Directorate, AHW Directorate, FC Directorate and CLVCE. Then this draft is to be endorsed by BFSA head officers, which is prerequisite to be finally adopted and signed by the Minister of Agriculture and Food and forwarded to DG (SANCO).

Within the process of this drafting, the experts of the aforementioned directorates are the ones to take into account all the relevant requirements of Directive 96/23 and the relevant application of secondary legislation for VMP usage and MRLs. They are responsible to identify and specify in the plan, the residues that are to be subject to monitoring, the matrixes that should be controlled and the number of samples for the next calendar year. These experts would decide for these NRCP elements after they have analysed all the data and relevant information gathered by and received from all the District Food Safety Directorates (the BFSA territorial units) that cover the following topics:

1. VMPs used in farmer practices;
2. numbers of farming animals countrywide broken by species, categories and age groups;
3. the manufactured amounts of raw materials and products of animal origin;
4. financial resources allocated to BFSA and testing capacities of CLVCE.

Any sampling provided for in and performed for the purposes of the NRCP is done by specifically designated OVs employed by RFSD. It is also at district level, where respective regional plans for monitoring control of residues are developed and then forwarded for approval into the LAD within BFSA. In each RFSD there is one OV designated for NRCP and responsible for its implementation.

All the samples taken under the NRCP are forwarded into the CLVCE. In case of non-compliances, the CLVSE must immediately inform directly the BFSA Executive Director and the LAD, CVMP Directorate and the relevant RFSD to decide the appropriate actions to identify the origin of contamination of animal(s) or product(s), of which respective sample(s) have been taken. The monitoring of products imported into EU from third countries is also part of the NRCP and it is one of the aspects of the border controls performed by border inspection posts (BIPs).

Laboratories

The CLVCE is the only laboratory in the country for controls of residual amounts of substances subject to sampling and analysis provided for in the NRCP. It is accredited in accordance with the requirements of ISO 17025 by the national Bulgarian accreditation body.

The LAD in co-operation with Food control Directorate, Control on veterinary medical products Directorate, Animal health and welfare Directorate, Plant protection products and fertilizers Directorate and the specialised structures CLVCE and CLCTC, prepare annually monitoring programs:

1. National monitoring program for control of residues of veterinary medical products and contaminants from the environment in live animals and products of animal origin (NMPCR) in accordance with Directive 96/23/EC;

The NMPCR is approved by the Minister of agriculture and food and by 30 March each year is send for approval also to the European Commission;

2. National monitoring program for pesticide residues in and on foods of animal and non animals origin, in accordance with Regulation (EC) No 915/2010 on co-ordinated multi annual control program of the Community (NMPPR).

The sampling for NMPCR and NMPPR is performed by the inspectors within the RFSD throughout the country and LAD co-ordinates the implementation of the monitoring programs.

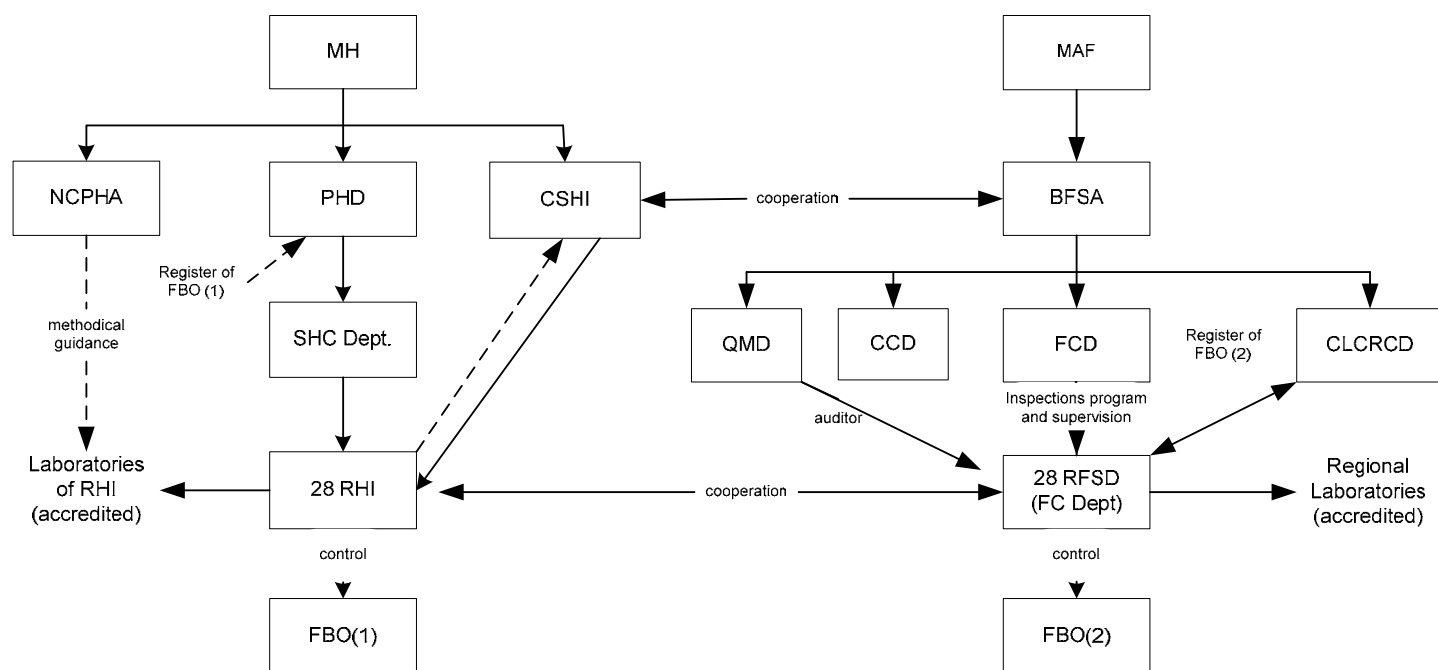
The testing of the samples for NMPCR is carried out in CLVCE. The following tests on groups of substances under Annex I of Directive 96/23 can not be analyzed in CLVCE:

1. A2 for residues of Antithyroid agents in meat and urine matrixes – CLVCE developed analyse for residues of A2;
2. Group A6 residue Nitrofurans in honey matrix – SGS has changed their scope of accreditation and excluded Nitrofurans in honey matrix;
3. Group B2b residue Anticoccidials, including nitroimidazoles in meat matrix and eggs – SGS has changed their scope of accreditation and excluded Anticoccidials in meat matrix and eggs;
4. Group B2c residue Pyrethroids in meat and honey matrixes – Samples for Pyrethroids in meat are outsourced in SGS Bulgaria, SGS has changed their scope of accreditation and excluded Pyrethroids in honey matrix;
5. Group B2e for residues of Non-steroidal anti-inflammatory drugs (NSAIDs) in meat and milk matrixes – CLVCE developed analyse for residues of NSAIDs in milk; meat samples are outsourced in Belgium;

The CA signed a contract - with 3 laboratories of SGS - in Belgium, France and Bulgaria. But this contract was suspended for group A6 – Nitrofurans in honey; B2b – Anticoccidials in meat and eggs and B2c Pyretroides in honey because this matrices and methods are out of scope of accreditation in there moment. Another procedure for a new contract for the unanalysed samples is in progress.

The testing of samples for NMPPR is carried out in CLVCE and in CLCTC. When non-compliances are found, a letter with the results from the analyses is sent to the Executive Director of the BFSa and to the director of the relevant RFSD, where the sample was taken. For every case of non compliance an investigation is initialized by the director of the RFSD for the purpose to clarify the reasons for the presence of residues in animals and products and contamination of the environment. After the detection of the source for contamination, relevant measures are taken to avoid future non compliances in accordance with national and EU legislation.

2.7 Control system for foodstuffs and food hygiene and GMOs



| | |
|-----------------|--|
| MH | Ministry of Health |
| MAF | Ministry of Agriculture and Food |
| BFSA | Bulgarian Food Safety Agency |
| FCD | Food Control Directorate |
| QMD | Quality Management Directorate |
| RFSD | Regional Food Safety Directorate |
| CLCRCD | Central Laboratory for Chemical Research and Control Directorate |
| CSHI | Chief State Health Inspector |
| RHI | Regional Health Inspectorate |
| NCPHA | National Centre of Public Health and Analysis |
| PHD | Public Health Directorate |
| SHC Dept | State Health Control Department |
| FBO(1) | Food Business Operators – production of bottled natural mineral spring and table water |
| FBO(2) | Food Business Operators |

- establishments producing or processing food of non-animal origin, ingredients and food contact materials
- retail trading food of non-animal origin solely
- retail both trading foods on non-animal origin and foods of animal origin

Competent authorities

The central competent authority is BFSA, respectively FCD. FCD co-ordinates and monitors the activity of all 28 RFSD. Inspectors of Food Control Department in each RFSD have carried out official controls in establishments producing or processing food of non-animal origin, food additives, food ingredients, food contact materials. They have carried out official controls in general activity establishments for food of non animal origin, retail establishments trading products of non-animal origin solely and retail establishments both trading products of non-animal origin and products of animal origin.

Approval and registration of food premises

The establishments are evaluated by a two-step evaluation procedure. (1) The first step is the submission of an application form with self assessment (please detail what you mean for self assessment) of the food business operator to the relevant RFSD. With an order issued by the Director of the relevant RFSD the regional commission is appointed, which, carries out an audit in the establishment to check compliance with EU requirements and National legislation.

Registration of FBOs retail trading takes place at regional level. A commission of inspectors of FC Department is responsible for the registration of FBOs where food of animal and non-animal origin is sold.

The register of all FBOs in Bulgaria is kept centrally by the BFSA. Software for the national register of establishments is under development. The list of approved establishments for intra-EU trade is published on the internet site of BFSA: <http://www.babh.government.bg/bg/registers.html>.

The register of all FBOs retail trading (catering, retail outlets, supermarkets, etc.) is kept centrally by the BFSA and the software for this national register is under development. When finalised, it will be published on internet site of BFSA.

Official controls of food premises

The FCD prepares an annual inspection programme and supervises its implementation. It also prepares manuals, instructions and checklists for the purpose of inspections and audits. Each RFSD develops a detailed annual programme for official controls of each FBO in the region. The frequency of visits is determined by evaluation of risk assessment which is made in accordance with “Instructions on the Application of Multi-annual National Control Plan of Raw Materials, Foods, Food ingredients, Food Additives in Food and Materials in Contact with Food 2011”. The RFSD reports the results of the controls to the FCD on a monthly basis about establishments and on a weekly basis about retail trading.

The FCD has developed instructions on the implementation of the MANCP when necessary. Based on these instructions and the criteria for risk assessment, each RFSD draws up a plan for official controls for each establishment and retail trading. The plan includes the frequency of control exercised by the inspectors and heads of the FCD. The last review of the instruction took place in May 2011.

The total number of inspectors from FCD within the RFSD carrying out the control is 989.

The QMD performs audits of the RFD. These also include the audits of activities of FCD.

HACCP and Good Hygiene Practice Guides

Under the Food Law, all FBOs must implement and maintain procedures based on HACCP principles. The implementation of HACCP systems is checked by the RFSD. Training for inspectors of the RFSD in auditing HACCP based systems is provided.

Guides to Good Hygiene Practice are developed by branch organisations of the food industry in consultation with other interested parties such as consumer associations and competent authorities.

RASFF

The AHFSD of the MAF is the National Contact Point (NCP). The NCP co-ordinates the activities of the contact points of the MAF, MH, Bulgarian Food Safety Agency, Commission for Consumer Protection, Executive Agency on Vine and Wine, Ministry of Defense, Ministry of Interior and the Ministry of Justice. The structure, functions and activities of each contact point is described in the RASFF manual of procedures.

The NCP is staffed with three experts and an expert reachable outside hours for emergency communications on a 24-hour/7-day-a-week basis. The NCP co-ordinates the activities of the Competent Contact Points (CCP), located in the BFSA, MH, Commission for Consumer Protection and Executive Agency on Vine and Wine.

The structure of the system includes a central management of BFSA with three Competent Contact Points (FECD, FCD, BCD), including the RAC, 28 RFSD of BFSA, 8 BIPs of BFSA, the CLVCE, the NDVRI, the National Centre of Radiobiology and Radiation Protection (NCRRP), the NCPHA, the MH and 28 regional RHI. NCP assess incoming notifications received by the European Commission and send them without undue delay to the CCP to take the necessary measures and actions. The NCP receives, validates and sends notifications to the EC, which are prepared on the basis of the inspections carried out by the CA in the territory of Bulgaria.

Laboratories

Laboratory analyses are carried out by the official control laboratories under the MAF as well as by the 6 laboratories of the RHI, NCPHA and NCPP, designated for official control of food under agreement with No RD-28-280/12.10.2011 between MH and MAF. Within the 6 laboratories of the RHIs analyses are performed for pesticide residues, mycotoxins, heavy metals and microbiological analyses of food of plant origin. They perform all chemical, toxicological and microbiological analyses. The NCPHA performs testing for food contact materials, colorants and GMO, and the NCPP identification of the exposure to ionizing radiation of food. All laboratories of the RHI are accredited to EN ISO/IEC 17025.

The CLCTC carries out testing of mycotoxins in food of plant origin. The CLCTC is accredited under EN ISO/IEC 17025 and nominated as NRL. The CLCTC carries out testing for pesticide residues, mycotoxins, heavy metals and nitrates content in food of plant origin. The CLCTC is nominated as NRL for pesticide residues in fruit and vegetable, for single pesticide residue methods as well as for mycotoxins in food of plant origin and accredited under EN ISO/IEC 17025.

In the CLVCE testing is performed of raw materials and products of plant origin for environmental contaminants - chemical elements and technogenic gamma-emitting radio nuclides.

Food borne illness

Salmonella is the principal cause of food borne illness followed by *Staphylococcus Aureus* and *Shigella*. Meat and meat products, eggs and confectionary are the most common foodstuffs implicated. A new Ordinance № 9 of 17 November 2011 on the procedures for reporting, investigation and registration of food illness outbreak and procedures for sampling has been published. The ordinance co-ordinates the activities of the regional structures of MH and MAF to investigate the cases of food borne diseases-outbreaks.

GMO

Competent authorities and controls

The competencies for controls of GMO, GM food and GM feed are shared between the FCD and the FeCD within BFSA.

Under the requirements of the Feed Law, transposing the relevant European legislation, FeCD is responsible for controlling the placing on the market and labelling of feedingstuffs, which contain or are consisted of GMO. The FeCD has worked out a risk assessment and risk analysis concerning GM feed as well as a plan for control based on the multiannual plan. The plan is executed within the frame of the Annual plan for controlling feedingstuffs.

Physical control is executed through the Regional Directorates of the agency. Control is carried out within the country and includes sampling and checking for compliance with the requirements for labelling.

Control is focused on the implementation of the requirements of Regulation (EC) No. 1829/2003 and No. 1830/2003. Controls are carried out by checking the products, their labelling and the accompanied documentation. Regular sampling is applied to consignments imported from third countries or placed on the market and distributed from other MS. The samples for GM food are analysed in the MH's laboratory in Sofia.

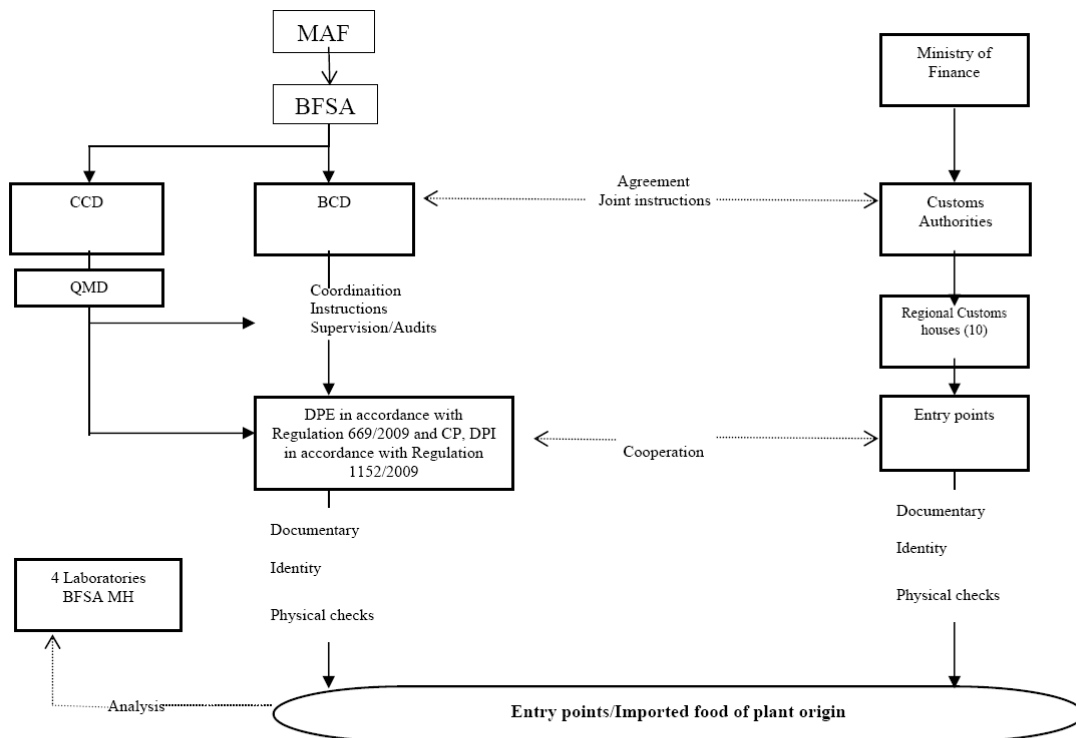
Within the MAF and according to the Law on GMO, the Food Law and Feed Law, the BFSA is responsible for control of raw material for feed and food use in processing establishments, placed on the market and import and export of food and feed. BFSA controls marketing, import and export of phytosanitary and veterinary medicinal products, containing, produced or including GMOs.

The Executive Agency for Plant Variety Testing (EAPVT) controls the presence of GMO during import, export and marketing of seed and planting material as well as variety testing field trials. The BFSA is responsible for the control of commercial cultivation of GM plants.

Laboratories

The National Reference Laboratory for GM food is in NCPHA under MH. The laboratory is accredited to ISO 17025 and performs analyses of GM food for the purposes of the official control.

2.8 Control system for imports of food of plant origin



| | |
|--------------|--------------------------------------|
| DPE | Designated points of entry |
| CP | Control points |
| DPI - | Designated points for import |
| CA | Customs Authorities |
| BCD | Border Control Directorate |
| CCD | Coordination and control Directorate |
| QMD | Quality management Directorate |
| MAF | Ministry of Agriculture and Food |
| MF | Ministry of Finance |
| MH | Ministry of Health |
| BFSA | Bulgarian Food Safety Agency |

Competent authorities

The CCA for import of Food of Non-Animal Origin (FNAO) is the BFSA. The BCD has overall responsibility for controls on imports of foodstuffs of plant origin. The BCD co-ordinates and supervises the activities of the BIPs and Designated Points of Entry (DPEs) in the areas of import controls. It prepares and issues guidelines and instructions for the implementation of controls.

Import controls

All documentary, identity and physical checks of imported foodstuffs of plant origin are carried out at the points of entry by BFSA officials. The sampling of imported foodstuffs is according to the requirements of national and EU legislation.

There is an updated endorsed Instruction for co-operation between Customs and the BFSA that covers also the mutual activities on the control of import of food of non-animal origin. These products may enter into Bulgaria only via designated points of entry. Laboratory analyses are required for these foodstuffs and they are released only after compliant results are received.

| DPE | Border | Type | Approval |
|------------------|-----------|---------|---|
| Burgas | Black Sea | Port | HC, FNAO in accordance with Reg. 669/2009, 1152/2009, 1135/2009, 258/2010 |
| Kapitan Andreevo | Turkey | Road | HC, FNAO, in accordance with Reg. 669/2009 |
| Sofia | n.a. | Airport | HC, FNAO, in accordance with Reg. 669/2009, 1152/2009, 1135/2009, 258/2010. |
| Varna | Black Sea | Port | HC, FNAO Reg. 669/2009, 1152/2009, 1135/2009, 258/2010 |
| CP - Plovdiv | FYROM | Road | HC, FNAO Reg. 669/2009, 1152/2009, 1135/2009, 258/2010 |

Laboratories

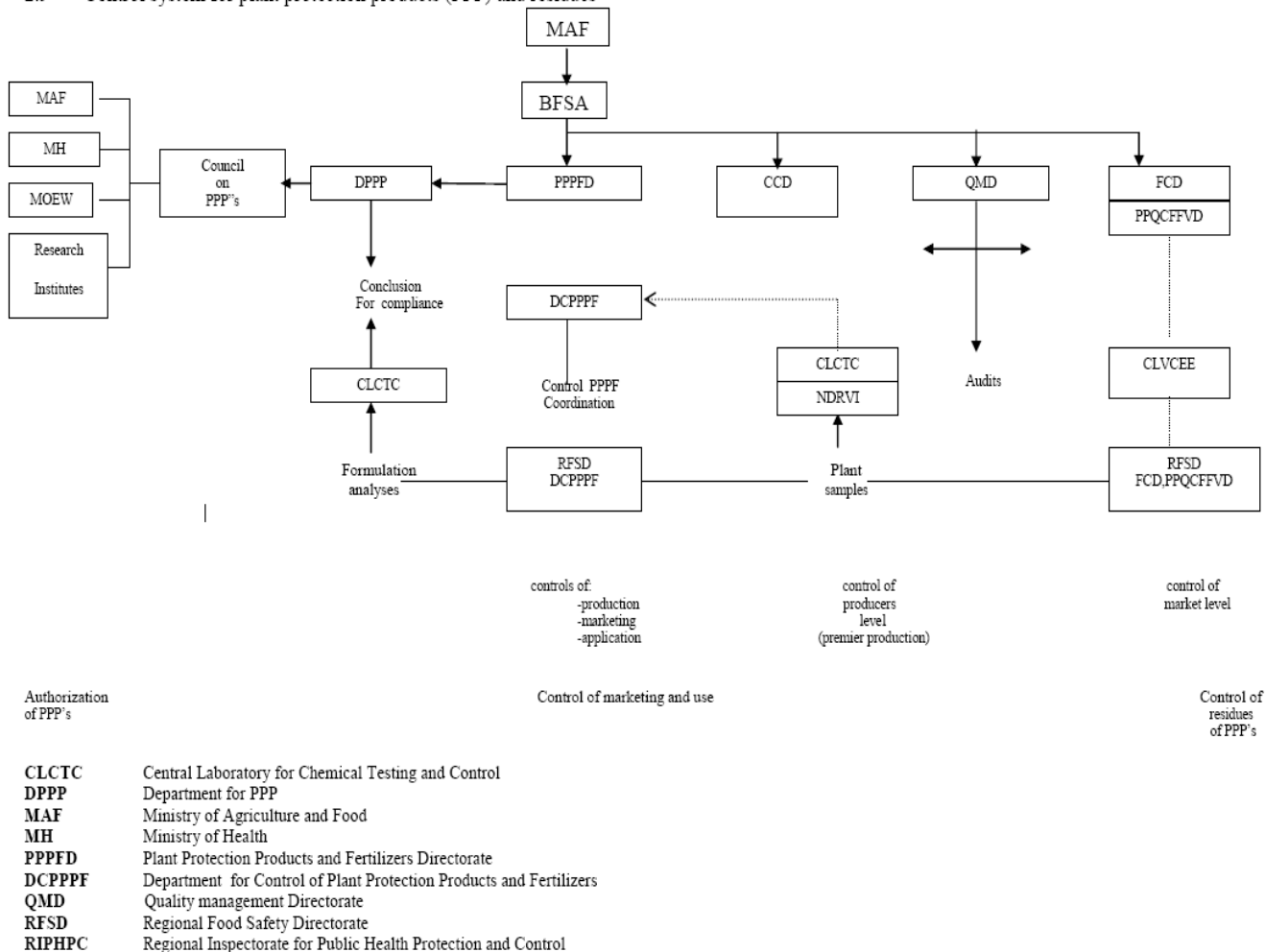
Laboratories that are used for analyses of imported foodstuffs of plant origin in accordance with Regulation (EC) No 669/2009 are within the MH. The laboratory in RHI Sofia is for certain pesticide residues. Within the BFSA, the laboratory designated for analyses of foods of plant origin is the CLCTC (mycotoxins, pesticides and heavy metals with regard to Regulation (EC) No 669/2009) and CLVCE for radioactivity.

Testing of samples for import of FNAO is performed by CLCTC within the BFSA and by RHI-Pleven within the MH. Pursuant to Regulation (EC) No 187/2011 of amending Annex I of Regulation (EC) No 669/2009, a contract No 27/09.06.2011 has been signed with RHI-Pleven for the analyses of imported foods of plant origin for certain pesticide residues for which at present CLCTC has no capacity (residues of methomyl, oxamyl, clofentezine, diafenthiuron, formetanate and thiophanate-methyl).

CLVCE performs testing of raw materials and imported products of plant origin for environmental contaminants, chemical elements and technogenic gamma-emitting radionuclides.

2.9 Control system for plant protection products (PPP) and residues

2.9 Control system for plant protection products (PPP) and residues



Control of marketing and use

Competent authorities

The BFSA is the CA for the authorisation of Plant Protection Products (PPP) through the Plant protection products and fertilizers Directorate (PPPPFD). The PPPFD methodologically co-ordinates the activities of RFS in the area of plant protection regarding the PPP and fertilizers. It also manages and co-ordinates the authorization of PPP for their placing on the market and use. A National Council on PPP has been established by order of the Minister of agriculture and food to act as a consultative body on PPP. Its members are representatives of the MAF, the MH, the Ministry of Environment and Water (MEW), the Bulgarian Academy of Science and Research Institutes.

Authorisation and registration of PPP

The dossier for authorisation of PPP is presented to the BFSA and subsequently reviewed and assessed by the MH, MEW and BFSA. Biological testing on new PPP for efficacy is performed in the 8 official bases of BFSA approved by order No RD 11-850/22.07.2011 of the executive director of BFSA (Plovdiv, Stara Zagora, Plevna, Russe, Vratsa, Bourgas, Veliko Tarnovo, Dobrich) and 4 more sub-divisions in Varna, Vidin, Haskovo and

Blagoevgrad. Final authorisation of PPP is issued by the BFSA on the basis of the Council's proposal. The BFSA maintains the documentation and register of authorised PPP. Up to the end of July 2011, there were 461 PPP authorised for marketing in Bulgaria and 205 active substances.

Official controls on marketing and use of PPP

BFSA is the CA for controls on import, marketing and application of PPPs, including labelling checks and checks for correspondence of the PPP with the indicators approved by the authorisation. Within the BFSA, the Department for Control of Plant Protection Products and Fertilizers prepares the annual national plans for control of marketing of PPPs and their use at farm level. It also co-ordinates and manages the control activities of the RFSD and issues checklists for inspections and instructions for taking samples.

Control is carried out by inspectors of the RFSD at production, import, packaging, storage, transport and at farm level. Each RFSD has an official responsible for PPPs control (planning and reporting). A total of 91 regional inspectors deal with the control of PPPs. Two checks are carried out annually on all PPPs producers as well as on repackaging companies. Control covers 100% of the wholesale trade and 80-100% of agricultural pharmacies. The RFSD annually controls 3-5% of the registered farmers for PPP usage. In case of suspicion, random control is carried out.

Formulation analyses of samples taken are performed by the CLCTC. Registers of PPP producers, traders and users are kept at both central and regional level.

A strategy for dealing with obsolete pesticides developed by the MEW is being implemented jointly with the municipalities.

Residues

Competent Authorities

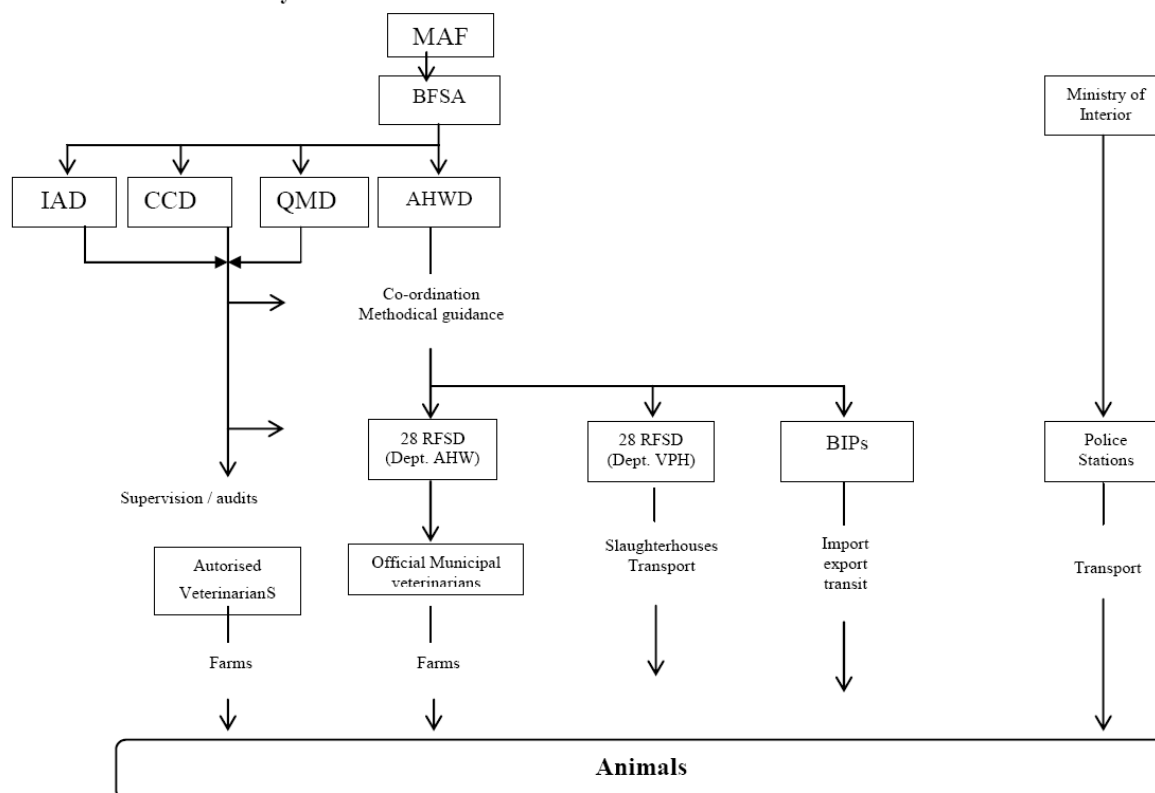
The BFSA is the CA for control and monitoring of pesticide residues in fresh, frozen, dried and processed fruit and vegetables at producer level and for monitoring pesticides residues in domestic and imported foodstuffs at market level.

Laboratories

The six laboratories of the RHI and the CLCTC perform analyses of pesticides residues in food of plant origin.

2.10 Control system for animal welfare

2.10 Control system for animal welfare



| | |
|-------------|---------------------------------------|
| BFSA | Bulgarian Food Safety Agency |
| RFSD | Regional Food Safety Directorate |
| AHWD | Animal Health and Welfare Directorate |
| CCD | Control and Coordination Directorate |
| QMD | Quality management Directorate |
| IAD | Internal Audit Directorate |
| BIP | Border Inspection Post |

Competent authorities

The CA for animal welfare is the BFSA. The AHWD is responsible for the control of animal health and welfare and its proper implementation, as well as preparation and active participation in the preparation of legislation in the respective area. The AHWD organises, co-ordinates and manages the activities of the RFSD. It issues instructions on inspection programmes, guidelines, protocols and forms for inspections, and manuals for farmers. It also organises training for inspectors involved in welfare checks. The updated documents regarding animal welfare issues are published on the BFSA website:

http://babh.government.bg/bg/actualno-department-health&article_id=107.html

The CCD performs audits at all administrative levels (AHWD, RFSD, OMV and APV). These include audits in the animal welfare area.

Official controls on farm and at slaughter

Animal welfare control plans are developed at regional level and submitted to the AHWD for approval. With the adoption of the new Animal Protection Law, the control plans are due to be prepared centrally.

Checks on animal welfare are carried out by inspectors of the RFSD and official veterinarians at BIPs. In each of the 28 RFSD, one official veterinarian is responsible for animal welfare issues. The OMV carry out checks on animal welfare requirements. The inspectors of the FCD of the RFSD are responsible for animal welfare checks in slaughterhouses.

A summary report on animal welfare inspections performed in each region is submitted by the RFSD to the AHWD twice a year.

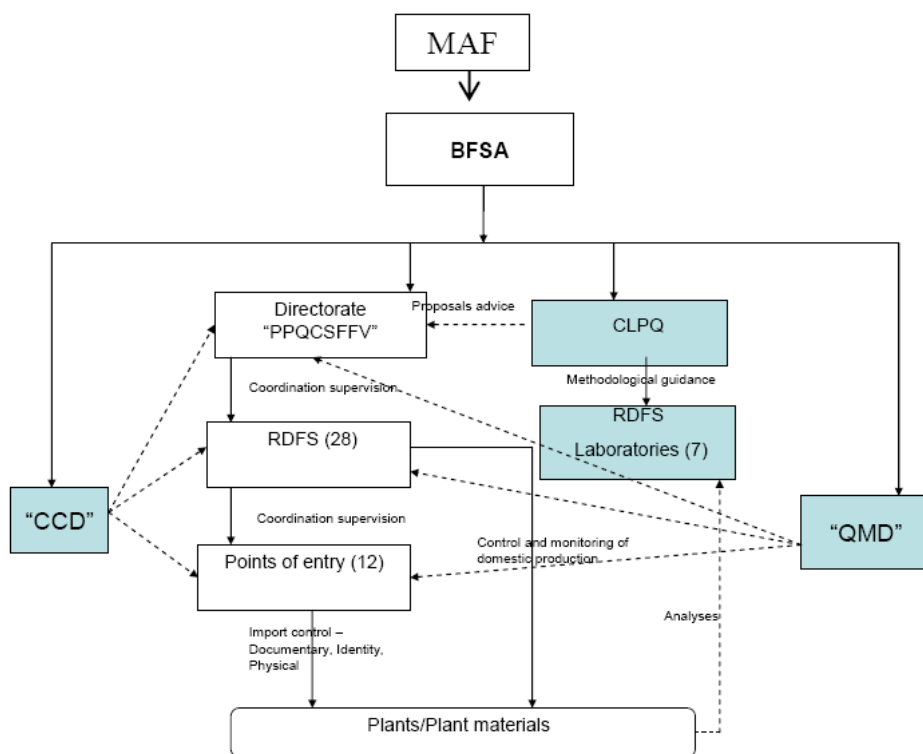
Official controls during transport

The Animal Protection Law and the Law on veterinary activity provide the legal basis for the police to perform animal welfare controls on transport. An Ordinance on co-operation and joint actions by the veterinary services and police, on transport checks was published in the State Gazette in 2011.

According to the MANCP checks are carried out at place of loading, place of destination, at markets, at BIPs and on the road.

Veterinarians in the BIPs check the animal welfare transport requirements at import, export and transit of animals.

2.11 Control system for plant health



| | |
|------------------|--|
| CLPQ | Central Laboratory for Plant Quarantine |
| MAF | Ministry of Agriculture and Food |
| BFSA | Bulgarian Food Safety Agency |
| PPQCSFFVD | Plant Protection and Quality Control and Safety of Fresh Fruits and Vegetables Directorate |
| RFSD | Regional Food Safety Directorate |

Competent authorities

The CCA for plant health issues is the BFSA, Plant protection and quality control of fresh fruits and vegetables Directorate (PPQCFVVD).

PPQCFVVD is responsible for the phytosanitary control of plants and plant products on the territory of the country.

The directorate:

- Conducts monitoring of plants in cultivated areas (including fields, nurseries, gardens, greenhouses and laboratories) and wild flora, as well as monitoring of storage and transport of plants and plant products, the occurrence, outbreak and spread of pests and their control.
- Inspects consignments of plants and plant products object of international trade and where appropriate inspects also other regulated articles to prevent the introduction and / or spread of pests.
- Regulates compliance of quality of fresh fruits and vegetables according to the national legislation for quality and maintain a national register of traders of fresh fruit and vegetables.

The Phytosanitary Control Department (PCD) of PPQCFVD operates in the field of harmful organism controls and is responsible for legislation drafting, planning and co-ordinating inspections at places of production, import, export and transit, and also for surveys and training of personnel. The Department employs five staff. It co-ordinates and supervises the activities of the RFSD on plant quarantine issues. It issues orders and guidelines for the regional inspectors. The co-ordination of laboratory activities (sampling and analyses) is mainly delegated to the CLPQ.

The RFSD are responsible for enforcement of legislation in the regions. They carry out inspections at the place of production; surveys; import and export certification. They also operate the alert system for producers as regards identification of pests and application of plant protection products.

Internal market controls

Monitoring programmes are prepared annually by the PCD and CLPQ. There are nine regional-based reporters for each of the nine monitoring programmes (potatoes, fruit trees, vine planting material, greenhouse plants, strawberries, forest species, *Diabrotica virgifera virgifera*, *Phytophthora ramorum* and ornamental plants). Reports of the activities carried out by the RFSD are sent monthly and each semester to the PCD. This information is compiled in an annual report which is subsequently used to establish the monitoring programmes for the following years.

Import controls

There are 12 points of entry for goods subject to plant health controls:

| BIP | Type | Border |
|------------------------|---------------|-----------|
| Kapitan Andreevo | Road | Turkey |
| Svilengrad | Railway | Turkey |
| Zlatarevo | Road | Macedonia |
| Gueshevo | Road | Macedonia |
| Kalotina/ Dimitrovgrad | Road/ Railway | Serbia |
| Vrushka chukka | Road | Serbia |
| Bregovo | Road | Serbia |
| Burgas | Port | n.a. |
| Varna | Port | n.a. |
| Vidin | Port | n.a. |
| Ruse | Port | n.a. |
| Sofia | Airport | n.a. |

At the points of entry, plant health inspectors carry out documentary, identity and physical checks. There are 44 inspectors employed at the plant health BIPs. Samples for analysis are taken in cases where presence of harmful organisms is suspected, or if the article is included in a special list (seeds and planting material). Once the consignment has been checked and is in compliance with the plant health provisions, it may be cleared by the Customs and released for free circulation.

Laboratories

The CLPQ is a NRL for plant health. It carries out plant health tests of imported and domestic plants, plant products, soil and other materials, conduct a final diagnosis and identification and validates the positive results of the analyses made by the 7 regional

diagnostic laboratories on plant health. The CLPQ is also involved in the co-ordination of the activities of the RFSD, issuing methodological guidelines for inspection and drafting monitoring programmes and provides training and instructions to staff on diagnostics and identification of pests. The CLPQ is located in Sofia and has a branch which is specialised in potato analyses in Samokov.

Laboratories are attached to each RFSD (except the Sofia-regional and Sofia -city), where tests are carried out.

Plant diseases

The tables below give the overview of outbreaks of quarantine pests on domestic materials for the period 2007-2011.

| Year | Pest | Crop | Area of outbreak | Measures taken |
|-------------------------|---|----------------------|--|---|
| 2007 | <i>Colletotrichum acutatum</i> Simmod | Strawberry | 12,6 ha | Treatment |
| | <i>Xanthomonas arboricola</i> pv. <i>pruni</i> | Sour cherry | 5 ha | destroyed 50 fruit trees |
| | <i>Clavibacter michiganensis</i> subsp. <i>sepedonicus</i> | Potato | 60,35 ha | 19579 kg of infected potatoes are destroyed and change crop |
| | <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> | Tomato | 7,7 ha | Prescriptions to destroyed contamination plants, to chemical treatment, disinfection and crop change. |
| | <i>Erwinia amylovora</i> | Fruit trees | 1,8 ha | Destroyed: 1,3 ha mother garden, Mother trees – 32 pcs. Trees in 0,43 ha garden, Saplings – 1252 pcs. |
| | Pear decline Phytoplasma | Pear | 0,4 ha | Destroyed 11 mother trees |
| | Apple Proliferation Phytoplasma | Apple | 0,5 ha | Destroyed 2 mother trees |
| | Strawberry latent ringspot virus (SLRSV) | Strawberry | 11,7 ha | Scheduling of strawberry plots for future observation and destroyed all plants around infected |
| | Strawberry mild yellow edge virus (SMYeV) | Strawberry | 10,6 ha | Scheduling of strawberry plots for future observation and destroyed all plants around infected |
| | Potato Stolbur Phytoplasma | Potato | 6 ha | destroyed all potato production |
| | Plum pox virus (PPV) | Fruit stone trees | Mother trees – 70 Saplings – 11150 pcs | Infected plants in the orchards and saplings are destroyed |
| | <i>G. rostochiensis</i> <i>G.pallida</i> | Potato | 106,8 ha | Registered plots and prescribed measures |
| | <i>Liriomyza huidobrensis</i> | Tomato and cucumbers | 17,25 ha | Prescriptions for chemical treatment |
| | <i>Bemisia tabaci</i> | Pot flower | 2,8 ha | Prescriptions for chemical treatment and infection destroying |
| | <i>Diabrotica virgifera virgifera</i> | Maize | 1175 ha | Confirmation for infection in a 8 new area in country |
| <i>Opogona sacchari</i> | Pot flowers | 0,05 ha | Destroyed infected 3 plants | |
| 2008 | <i>Cryphonectria parasitica</i> | chestnut | 9 samples | Destroyed |
| | <i>Erwinia amylovora</i> | Fruit trees | 3 mother tree | destroyed |
| | <i>Clavibacter michiganensis</i> subsp. <i>sepedonicus</i> | Potato | 28,3 ha | Destroyed |
| | <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> | Tomato | 3,83 ha | Prescriptions to destroyed contamination plants, to chemical treatment, disinfection and crop change. |
| | Strawberry mild yellow edge virus (SMYeV) | Strawberry | 2 ha | Scheduling of strawberry plots for future observation and destroyed all plants around infected |
| | Plum pox virus (PPV) | Fruit stone trees | Mother trees – 21 pcs Saplings – 3257 pcs | Destroyed |
| | <i>G. rostochiensis</i> <i>G.pallida</i> | Potato | 15,5 ha | Registered plots and prescribed measures |
| | <i>Bemisia tabaci</i> | Pot flower | 0,8 ha | Prescriptions for chemical treatment and infection destroying |

| Year | Pest | Crop | Area of outbreak | Measures taken |
|-------------------------------|--|-------------------|--|--|
| 2009 | <i>Xanthomonas campestris</i> pv. <i>vesicatoria</i> | Pepper | 5,2 ha | Registered plots and prescribed measures |
| | <i>Bemisia tabaci</i> | Pot flower | 0,3 ha | 152 pot flower-destroyed; Prescriptions for chemical treatment and infection |
| | <i>Opogona sacchari</i> | Pot flower | 9 pots | Destroyed |
| | <i>Liriomyza huidobrensis</i> | Tomato | 2,7 ha | Prescriptions for chemical treatment |
| | <i>Liriomyza bryoniae</i> | Tomato | 47 ha | Prescriptions for chemical treatment and infection and infection |
| 2010 | <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> | Tomato | 2 samples | Destroyed |
| | <i>Clavibacter michiganensis</i> subsp. <i>sepedonicus</i> | Potato | 45 ha | Destroyed |
| | <i>Xanthomonas campestris</i> pv. <i>vesicatoria</i> | Pepper | 15,3 ha | Registered plots and prescribed measures |
| | <i>Erwinia amylovora</i> | Fruit tree | One mother tree | Destroyed |
| | Plum pox virus (PPV) | Fruit stone trees | Mother trees - 14 | Destroyed |
| | AP Phytoplasma | apple | One mother tree | Destroyed |
| | PD Phytoplasma | Pear | 10 mother trees | Destroyed |
| | Apricot chlorotic leafroll Phytoplasma | Apricot | One mother tree | Destroyed |
| | <i>Cryphonectria parasitica</i> | Chestnut | 3 samples | Destroyed |
| | <i>Plasmopara helianthi</i> | Sun flower | 3 samples | |
| | <i>Ditylenchus destructor</i> | Potato | 1 sample | Registered plots and prescribed measures |
| | <i>Aphelenchoides besseyi</i> | Rice | 13 samples | Registered plots and prescribed measures |
| | <i>G. rostochiensis</i> <i>G.pallida</i> | Potato | 103 ha | Registered plots and prescribed measures |
| | <i>Bemisia tabaci</i> | Pot flower | 3 pots | Destroyed |
| | <i>Diabrotica virgifera virgifera</i> | Maize | | Confirmation for infection in a 1 new area in country |
| <i>Liriomyza bryoniae</i> | Tomato | 1 ha | Prescriptions for chemical treatment and infection | |
| 2011 June | <i>Clavibacter michiganensis</i> subsp. <i>sepedonicus</i> | Potato | 0,6 ha | Destroyed |
| | <i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i> | Tomato | 0,4 ha | Prescriptions to destroyed contamination plants, to chemical treatment, disinfection and crop change |
| | <i>Xanthomonas campestris</i> pv. <i>vesicatoria</i> | Tomato | 9 ha | Registered plots and prescribed measures |
| | Plum pox virus (PPV) | Fruit stone trees | 11 mother trees | Destroyed |
| | PD Phytoplasma | Pear | One mother tree | Destroyed |
| | PepMV | Tomato | 11 samples 260 ha | Prescriptions for chemical treatment and infection |
| | <i>Cryphonectria parasitica</i> | Chestnut | 2 trees | Destroyed |
| | <i>Bemisia tabaci</i> | Pot flower | 1 | Destroyed |
| | <i>Liriomyza bryoniae</i> | Tomato | 263 ha | Prescriptions for chemical treatment and infection |
| <i>Liriomyza huidobrensis</i> | Cucumber | 3 ha | Prescriptions for chemical treatment and infection | |

Number of Control Staff in Bulgaria
Summary Table

| Competent authority | Staff |
|---|--------------|
| Ministry of Agriculture and Food | 23 |
| - Animal Health and Food Safety Directorate | 23 |
| Bulgarian Food Safety Agency | 2,798 |
| Ministry of Health | 43 |
| Directorate for Public Health | 5 |
| Regional Inspectorates | 38 |
| TOTAL | 2,864 |

Note: All staff numbers are recorded as *full-time equivalents*

² Statistics on control staff have been provided by Bulgaria on a non-standardised basis.

ANNEX II – ACRONYMS, ABBREVIATIONS AND SPECIAL TERM

| ACRONYM | DESCRIPTION |
|----------------------|---|
| ABP | Animal by-products |
| AMR | Antimicrobial Resistance |
| AHFS | Animal Health and Food Safety Directorate |
| AHWD | Animal Health and Welfare Directorate |
| APV | Authorised Private Veterinarians |
| BAS | Bulgarian Accreditation Service |
| BCD | Border Control Directorate |
| BIP | Border Inspection Post |
| BFSA | Bulgarian Food Safety Agency |
| BSE | Bovine Spongiform Encephalopathy |
| BTSF | Better Training for Safer Food |
| CA | Competent Authority |
| CCA | Central Competent Authority |
| CCD | Co-ordination and control Directorate |
| CCP | Competent Contact Points |
| CDA | Chief Directorate of Agriculture |
| CDB | Central Database |
| CLCRCD | Central Laboratory for Chemical Research and Control Directorate |
| CLCTC | Central Laboratory for Chemical Testing and Control |
| CLPQ | Central Laboratory for Plant Quarantine |
| CLVCE | Central Laboratory for Veterinary Control and Ecology |
| CSF | Classical Swine Fever |
| CSHI | Chief State Health Inspector |
| CVMPD | Control of VMPs Directorate |
| DCPPF | Department for Control of Plant Protection Products and Fertilizers |
| DG SANCO | Directorate General for Health and Consumer Protection |
| DPE | Designated Points of Entry |
| DPPP | Department for Plant Protection Products |
| EC | European Commission |
| EURL | European Reference Laboratory |
| EVA | Equine Viral Disease |
| FBO | Food Business Operator |
| EAPVT | Executive Agency for Plant Variety Testing |
| FCD | Food Control Directorate |
| FC Department | Food Control Department |
| FeCD | Feed Control Directorate |
| FMD | Foot and Mouth Disease |
| FNAO | Food of Non-Animal Origin |
| FTE | Full Time Equivalent |
| FVO | Food and Veterinary Office |
| GFA | General Follow-up Audit |
| GMF | Genetically Modified Foods |
| GMO | Genetically Modified Organism |
| HACCP | Hazard Analysis Critical Control Point |

| ACRONYM | DESCRIPTION |
|------------------|--|
| I&R | Identification and Registration |
| LAD | Laboratory Activities Directorate |
| MAF | Ministry of Agriculture and Food |
| MANCP | Multi-Annual National Control Plan |
| MBM | Meat and Bone Meals |
| MEW | Ministry of Environment and Waters |
| MH | Ministry of Health |
| MRL | Maximum Residue Limit |
| NCP | National Contact Point |
| NCPHA | National Centre of Public Health and Analyses |
| NCRRP | National Centre of Radiology and radiation protection |
| NDRVI | National Diagnostic and Research Veterinary Institute |
| NGFS | National Grain and Feed Service |
| NPPS | National Plant Protection Service |
| NRCAH | National Reference Centre on Animal Health |
| NRCP | National Residue Control Plan |
| NVS | National Veterinary Service |
| NRL | National Reference Laboratory |
| OMV | Official Municipal Veterinary |
| PCD | Phytosanitary Control Department |
| PHARE | Pre-accession Financial Instrument |
| PHD | Public Health Directorate |
| PPP | Plant Protection Product |
| PPPFD | Plant Protection Products and Fertilizers Directorate |
| PPQCSFFVD | Plant Protection and Quality Control and Safety of Fresh Fruits and Vegetables Directorate |
| QMD | Quality management Directorate |
| RAC | Risk Assessment Centre |
| RASFF | Rapid Alert System for Feed and Food |
| RFSD | Regional Food Safety Directorates |
| RHI | Regional Health inspectorates |
| RFSD | Regional Food Safety Directorate |
| RTL | Regional Testing Laboratories |
| SCFCAH | Standing Committee on Food Chain and Animal Health |
| SHC Dept | State Health Control Department |
| SRM | Specific Risk Material |
| TQD | Training and Qualification Directorate |
| TRACES | Trade Control and Expert System |
| TSE | Transmissible Spongiform Encephalopathy |
| VMP | Veterinary Medicinal Product |